Making the right choices in ITP management and care

A shared decision making toolkit for patients
Immune Thrombocytopenia (ITP) management and care shared decision making tool kit

This toolkit is for ITP patients and people who know someone with the condition. It helps to define what best practice collaborative decision making in ITP management and care looks like and provides a practical guide to help patients, carers and healthcare professionals achieve this.

The National Institute for Health and Care Excellence (NICE) has produced guidelines to support the implementation of shared decision making across all health care settings. This toolkit will help to facilitate NICE’s recommendations for shared decision making in ITP, including the use of patient decision aids and improved communication about risks, benefits and consequences with patients.

The making of this ITP management and care shared decision making tool kit

This toolkit was developed as a joint initiative between the ITP Support Association and UK ITP Forum via an expert Working Group. The group comprised of a diverse range of stakeholders with experience of ITP from treating and managing the condition to advising and supporting patients.

The ITP Support Association has received grant funding for the establishment of the Working Group and the development of these materials, from:

AMGEN  Sobi  Novartis
Principia  Grifols

Endorsements

This toolkit is endorsed by: Royal College of Pathologists, British Society for Haematology, ITP Support Association, UK ITP Forum; and

Genetic Alliance UK  Rare Disease UK  Royal College of General Practitioners

The Royal College of Physicians has reviewed and endorses the clinical content of this document.

Referencing this Booklet


Hard copies of the shared decision making toolkit are available to post to UK addresses.
Information about ITP (Immune Thrombocytopenia)

What is Immune Thrombocytopenia?
Immune thrombocytopenia is an autoimmune disorder (immune) causing a shortage of platelets (thrombocytes) and bruising. It is, in part, caused by destruction of platelets by autoantibodies, which are produced by the body’s immune system and are inappropriately directed against them. Autoantibodies may also be directed against elements in the bone marrow, megakaryocytes, which make platelets and their impact is to reduce platelet production. This increased destruction and reduced production act together and reduce the platelet count in the blood stream. The cause of the abnormal production of the autoantibodies is in general unknown.

Production of Platelets

Thrombopoietin (TPO) is produced by the liver and is the hormone responsible for megakaryocyte development and platelet production. The TPO hormone binds via the TPO receptor to stimulate the transition of megakaryocytes into platelets. Normally TPO levels are unmeasurable as TPO is used up in producing platelets. In ITP the TPO insufficiently stimulates the megakaryocytes to release platelets and remains detectable in the blood. Platelets are removed in the liver and spleen. Antibody-bound platelets and TPO are rapidly cleared by the spleen and TPO are removed in the liver.

What are platelets?
Platelets are one part of the blood clotting mechanism – they act by initiating the blood clotting process by ‘plugging’ any gaps in the blood vessel wall which may be caused by injury or even minimal trauma. Platelets are made in the bone marrow and released into the blood and a normal platelet count is 150 to 400 x 10^9 / L of blood. Anyone with a count of less than 100 would be considered thrombocytopenic (short of platelets). Bleeding rarely occurs until the platelet count is less than 30 but many patients with ITP will have a platelet count in single figures, particularly at presentation.

What causes ITP?
ITP occurs when the immune system mistakes platelets as foreign bodies and destroys them. It can happen after a virus, or in the very rare case of the administration of a vaccination or medication, but for most people the cause is unknown and may reflect a weakening of the immune system that occurs with age. In children it most commonly occurs following a viral infection. Although rare it may occur following many of the common childhood viral infections and in the majority is transient.

Autoimmune responses affect the rate of platelet production and platelet turnover

Normal rate of platelet production and turnover

Decreased platelet production

Increased platelet destruction

ITP that has just presented is known as ‘newly diagnosed ITP’, it may present acutely with bleeding problems or is frequently diagnosed unintentionally by a clinician via a blood test. In the latter group the condition may have been present over a long period undiagnosed so new patients are no longer termed ‘acute’. If the platelet count remains low after 3 months it will be called persistent ITP. If the platelet count has not returned to normal after 12 months it will be called chronic ITP.

Other causes of ITP
A low platelet count can be caused by other conditions so a series of tests will be needed to check for other potential causes, such as a blood disorder, rheumatoid or liver disease and viral infections. It may also be due to a drug effect. Such secondary causes may occur in up to 30% of all cases of low platelet count but this varies around the world.

Presentation of ITP
Up to a third of adult patients with ITP may have no symptoms at all, with their ITP only noticed from a routine blood test. In those who present with bleeding manifestations common findings include petechiae (pin prick rash of blood spots), bruising, nosebleeds, gum bleeds, black mouth blisters and heavy periods. Much more rarely bleeding may occur in the eyes, in the urine, from the stomach or gastrointestinal tract or into the brain.

It has been increasingly recognised that fatigue may be quite prominent and debilitating when the platelet count is low in ITP.

The incidence of ITP
In the UK the incidence of ITP is approximately 6 per 100,000 adults (which approximates to 2,400 new adult cases each year), many of whom will not know that they have it. As ITP in adults is usually a chronic disease it tends to be more persistent in the population and one study reviewing the UK GP database suggests a prevalence of up to 50 per 100,000. This increases with age being more prominent in the over 65’s. It is also more common in women and is not seen more frequently in any racial or ethnic group.
**How is ITP diagnosed?**

ITP is usually diagnosed by a blood test which shows that the platelet count is low, but the appearance of the blood is otherwise normal and the red blood cells and white blood cells are present in normal numbers. As outlined in ‘other causes of ITP’ a low platelet count can be caused by other conditions so a series of tests will be needed to check for other potential causes.

Extra blood tests may also be done at this time to check for rare clotting or immune diseases that can look similar to ITP. A bone marrow biopsy is usually unnecessary for the diagnosis but may be taken at a later stage if ITP is persistent, in any way not typical, or fails to respond to usual treatments.

**Who develops ITP?**

ITP is not an inherited condition and it can arise in any person, adult or child, at any stage in their life, but immune conditions such as thyroid disease, systemic lupus erythematosus and rheumatoid arthritis can have familial links.

ITP in adults is likely to be a long-term condition but is only severe in a small percentage of people. It is more common in women than men in middle age but this situation changes with age and the condition is more prominent in men over 60 than women. It is not more common in any racial or ethnic group.

It may be picked up in younger women during routine pregnancy blood tests, however in pregnancy the platelet count often falls to some extent and this natural decrease needs to be differentiated from true ITP.

ITP in adolescents is similar to that seen in children but 20% go on to develop chronic disease. Treatment follows the pattern in adults but it is important to be aware of the special problems relating to mood-changes, schooling, socialising and long-term treatment that may complicate management in this group.

This guide is to be used as an aid for adults with ITP. Further information about ITP in women during pregnancy can read ‘about ITP in women during pregnancy’ and available via links in the Further Information section.

**Living with ITP**

Most people with ITP lead full lives. Although ITP can be troublesome for some, for the majority it can be successfully managed, sometimes with treatment but more often than not without.

People with ITP choose to cope with their condition in different ways and it is common for patients to become very well informed on their condition. Being an active participant in treatment and lifestyle management decisions helps many patients to feel in control and helps ensure treatment is tailored appropriately.

**What is shared decision making?**

Shared decision making is when clinicians and patients work together in collaboration, putting people at the centre of decisions about their own treatment and care.

Shared decision making also supports people to develop the knowledge, skills, and confidence they need to manage and make informed decisions about their own health and health care.

**Why shared decision making matters**

For care to be enabling, the relationship between clinicians and patients needs to be a partnership rather than just the health care professional directing.

When patients and clinicians make decisions together:

- Both the clinician and patient understand what is important to the other
- Patients feel empowered to make informed choices and their treatment and care plan takes account of their perspective
- Health and other care professionals can tailor the care or treatment to the needs of the individual

**The importance of shared decision making mechanisms in ITP management and care**

For ITP patients:

- The care and support you receive should consider your needs and preferences
- You have the right to be involved in discussion and make decisions about your treatment and care, together with a healthcare professional
- You should feel empowered to clarify issues relating to your treatment and care with health care professionals
- Your circumstances may change, so it is important that your treatment plan is continuously reviewed and a joint decision is taken on the future approach
- For adolescents the treatment approach should be designed to allow normal life and activity, including schooling, as far as is possible. The potential impact of having a chronic condition and the effect of treatment, particularly steroids, on causing changes in mood should be explored and understood
For better prescribing:
Choosing the right therapy for ITP at the right time is often a difficult moment for those treating ITP patients. Many patients do not require treatment as a low platelet count alone is not a trigger unless associated with bleeding or the imminent risk of bleeding. Treatment decisions should be based on a mixture of the platelet count, bleeding problems, other medical conditions, separate drug treatment and level of activity. What is appropriate for an older individual would not necessarily be correct for a younger, more active individual. Treatment should also be guided by the patient attitude to the potential side-effects of treatment, tolerance of bruising and attitude to the risks and benefits of giving or withholding treatment.

Traditionally, the assessment of patient response to a treatment has been exclusively made by clinicians based on platelet count and clinical bleeding. However, updated guidelines emphasise that treatment choice should incorporate the patient’s perspective – towards a holistic approach to treatment and management of ITP in which a patient’s quality of life should be the primary focus. This should include an understanding of the potential risks and benefits of the available treatments.

The importance of patient education
Patient education can include information about all issues relating to ITP, including disease characteristics, symptoms, treatments and what the NHS/ patient care pathway looks like. Nurses and other care professionals provide a key role in educating patients and families about ITP, how it can affect lifestyle and relationships, treatment options, including benefits, side effects, dosing, routes of administration and duration, and how patients may need to adapt their lifestyle accordingly.

You should always feel empowered to ask your healthcare professionals about these issues and further patient education materials are available via the ITP Support Association website.

Crucially, patient and clinician collaboration improves understanding of the efficacy and side effects of therapy and provides the approach that may work best for a certain patient demographic.
Best practice in collaborative decision making: step-by-step guide

Presentation and management pathway

1. What are the modes of presentation:
   - Easy bruising
   - Petechial Haemorrhaging - small red marks on the eyes or skin
   - More severe bleeding
   - Low platelets picked up incidentally

2. What are the routes of presentation:
   - GP
   - Accident and Emergency Department (A&E)
   - Clinician for other medical condition

3. The next steps:
   - A series of tests to exclude underlying conditions and confirm diagnosis
   - Referral to A&E and/or
   - Referral to a Haematologist

4. What happens next:
   - A series of tests to exclude underlying conditions and confirm diagnosis

5. ITP confirmed

6. Stages 6-8 involve discussion and shared decision making.
   Information exchange:
   - Discussion with Haematologist, Clinical Nurse Specialist (CNS) and/or other team member
   - Watch and wait or institute treatment

7. Treatment decision:
   - Watch and wait or institute treatment

8. Follow up:
   - Review of patient response and disease progress
   - Discussion between clinician and patient to reinforce understanding of ITP and the explain the treatment and care options available
   - Collaborative decision made on ongoing management of the condition

Jump to section:
Following an ITP diagnosis – what to expect

When people are told they have ITP, it generates understandable questions about how the condition will affect their lifestyle. People diagnosed with ITP often feel shock, fear and potentially grief and denial at first. It is common for people to experience anxiety, depression and a loss of self-confidence, but with the right support all of these can be overcome. The diagram below provides an overview of the stages/patient pathway following an initial ITP diagnosis. This includes:

1. **Written confirmation**
   - Following diagnosis, a patient can expect an explanation of the diagnosis and a written copy detailing the diagnosis and consultation.

2. **Supporting information and emergency contacts**
   - An outline of any support information and details of the clinical team that will be looking after the patient should be provided. Information about who to contact in an emergency should also be shared.

3. **Confirmation of ongoing clinical support**
   - Details of a named consultant who will review the patient regularly should be established. In some cases patients will also be provided details of a clinical nurse specialist who as part of a multidisciplinary team (MDT) will be a regular point of contact.

**Your profile as an ITP patient**

For the duration of their treatment and care, patients with ITP should have regular appointments with specialist healthcare professionals in hospital-based haematology services and/or specialist ITP centres. However, there is significant variation in the experience of patients and the treatment and support they are provided with. Care may also take place on a haematology day unit. This unit also provides patients with a point of contact in an emergency and for general support and advice.

Patient support groups such as those facilitated by the ITP Support Association are a further avenue for providing patients with advice and coping strategies, which is key to their physical and mental health. The Association also has a number of Mentors, who are patients with ITP, who are available to discuss questions and worries, confidentially, on a one to one basis. They can be accessed by contacting the Association.

**Healthcare professionals you will engage with**

- **Primary care professionals** – e.g. GP, practice nurse or pharmacist, through services based in the community at a range of settings, including GP practices, local health centres, community clinics or your home. Professionals who work in primary care are generalists rather than specialists in a particular disease area like ITP; however, their general skills make them a potentially important source of support.

- **Clinical Nurse Specialist** – has specialist skills, knowledge and experience in caring for patients with ITP. They are key members of a multi-disciplinary team (MDT) involved in the management of ITP. Access to CNSs is currently not widespread with only a limited number in hospitals and specialised ITP centres.

- **Clinical Psychologist** – work within some specialist ITP centres to help people adjust and cope with their ITP, and its management.

- **Haematology Day Unit team** – a specialist team who provide a comprehensive service for patients with a variety of conditions including ITP, such units also provide patients with a point of contact in an emergency and for general support and advice. Patients may also have access to a pathologist who provide diagnostic and monitoring support for their condition.

- **Clinical Pharmacist** – most units also have a dedicated pharmacist, who will have in depth knowledge of the various drugs used and will be able to discuss their potential impact in detail.

- **Other MDT members** – a group of professionals drawn from one or more clinical disciplines who together make decisions regarding recommended ITP treatments.

**The importance of Quality of Life**

**Recent Studies**

Recent findings highlight that patients view quality of life as the most important factor in the treatment and management of the condition. Moreover, studies continue to be conducted in order to further understand how ITP impacts on a patient’s daily life.

**Fatigue**

The impact of ITP, especially chronic ITP, on patient quality of life can be substantial. The most difficult ITP symptom to treat is severe fatigue, reported in 39% to 59% of adult patients with ITP, and this can be under recognised by healthcare professionals.

**Mental Health**

ITP can lead to impaired quality of life across emotional, functional, reproductive, and health domains, in turn affecting mental health. These changes may be particularly marked in adolescents and need careful handling for both the patient and their family.

*During such discussions, nurses and other healthcare professionals can help patients and their families with the physiological and psychological effects of ITP by providing support in terms of active listening and asking questions, by providing information and by referral to appropriate resources.*

*Jump to section: Jump to section: Jump to section:*
Further information about ITP treatment options

Introduction to ITP treatments

Up to 40% of patients with ITP will require no treatment and in many the treatment will be short term and relatively mild.

In only a small proportion of patients, treatment will be ineffective or require intense long-term administration. There is currently no treatment that is guaranteed to cure ITP. Traditionally treatments include steroids, immune suppressive drugs or splenectomy. High-dose dexamethasone may be an alternative to Prednisolone, the most commonly used steroid.

Over the last decade, there have been innovations and changes in treatment practices. Rituximab is not licensed for ITP but has been used extensively since the early 2000s and acts by ‘damping down’ the immune system. A new class of drugs known as the thrombopoietin receptor agonists have been licensed for ITP and include; eltrombopag, romiplostim and avatrombopag, which all stimulate platelet production. More recently Fostamatinib has been licensed for use in ITP and acts by blocking the pathway in the cell that leads to platelet destruction. All these drugs are generally known by their trade names. The advantage of the newer drugs is that they do not have the immune suppressive action, of the traditional agents used and therefore lack the side effects of these classes of drugs.

Splenectomy (the removal of the spleen) is now far less commonly used and only recommended after failure of medical therapies and is dependent on age and co-existing medical problems. It is often now preceded by a radioisotope investigation to identify the sites of platelet destruction to increase the likelihood of surgical success.

In addition, patients may have the opportunity to take part in clinical trials and controlled studies that are performed before a new treatment is approved by the Medicines and Healthcare products Regulatory Agency (MHRA). It is important that patients are aware of new, developing therapies and should discuss the implications of proposed treatment in collaboration with a clinician before enrolling in a clinical trial. The best way to find the latest information on ITP clinical trials is by visiting the Be Part of Research or The UK ITP Forum website.

The diagram below provides recommendations to help patients live better with ITP:

- Taking non-ITP medications
- Sexual relations
- Physical activities
- Personal hygiene
- Travel
- Insurance
- Other

Recommendations to help Patients to Live Better with ITP

<table>
<thead>
<tr>
<th>Topic</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taking non-ITP medications</td>
<td>Avoid medicines that can potentially affect platelet count (blood-thinning agents, anti-inflammatory agents, platelet aggregation inhibitors); closely monitor patients who do require anticoagulants for managing other medical conditions. Use paracetamol-containing medications for pain and fever. Tell your clinician about all the medications you are on now and that you have previously been prescribed for ITP and all conditions.</td>
</tr>
<tr>
<td>Sexual relations</td>
<td>Not restricted, care should be exercised if platelet count is low and/or patient has active bleeding.</td>
</tr>
<tr>
<td>Physical activities</td>
<td>Avoid any activity with high risk of injury (combat and contact sports); wear gloves when working with knives or other tools and for gardening; wear protective clothing (helmets, knee, elbow or wrist pads).</td>
</tr>
<tr>
<td>Personal hygiene</td>
<td>Use soft toothbrush; avoid dental flossing with oral bleeding; maintain regular dental health assessments; use an electric shaver; avoid constipation, do not use suppositories or enemas. It is also recommended that you tell your dentist about all medications that you are on now and in the past for ITP and all conditions.</td>
</tr>
<tr>
<td>Travel</td>
<td>Air travel: undertake recommended in-flight exercises to prevent deep vein thrombosis, wear support stockings, avoid alcohol and drink plenty of water. When traveling outside the UK it is recommended that you carry a letter detailing your ITP diagnosis.</td>
</tr>
<tr>
<td>Other</td>
<td>Wear a medic alert/identification bracelet; carry an identification/health card with information on ITP. It is also advised that you make family and friends aware of your condition. Keep a note of medication you are on, dosage, and when you were prescribed.</td>
</tr>
</tbody>
</table>
The diagram below provides an overview of therapies for the treatment of ITP

Updated clinical guidance

Changes in the updated international consensus guidelines

It is recognised that over the past decade there has been a move away from focusing exclusively on increasing a patient’s platelet count. While still important, ITP is now regarded as much more than simply the patient’s platelet count. This is reflected in the Updated international consensus report on the investigation and management of primary immune thrombocytopenia, which provides recommendations on the diagnosis and management of ITP in children, adults and during pregnancy.

For example, steroids, while still useful, can have troublesome side effects, and the consensus recommends limiting prednisolone dose to 80mg daily maximum and length of course (first line) to 6–8 weeks maximum in adults (shorter if not responding) and earlier use of the thrombopoietin receptor agonists in those requiring further treatment. The American Society of Hematology has also updated its guidelines with very similar objectives to those from the international group.

The goals of therapy

It is important that treatment is always tailored to the individual, with many factors contributing to treatment decisions. Patients who can make decisions about their care and treatment in partnership with healthcare professionals are more satisfied with their care and are more likely to choose treatment in partnership with healthcare professionals are more satisfied with their care and are more likely to choose treatments based on their values and preferences rather than relying solely on the clinician’s advice.

Making the right ITP treatment decision

On the following page is a list of questions to help you think about the way you live and the treatments that will suit you best. Ask your ITP health professional if there is something about your situation that makes one treatment more appropriate for your lifestyle. Patients are urged to read and think about treatment options before discussing with your health professional. Understanding the implications of different treatments will help you consider which option will best suit your personal situation.

Questions to consider at the beginning of ITP treatment

Below is a list of questions to consider in advance of a treatment discussion:

1. List the activities you do now and want to keep doing throughout your ITP treatment and care (these may include socialising, hobbies, leisure, holidays, work, study)
2. List the questions or worries you have about ITP and its treatment
3. Does the frequency of taking treatment matter to you?
4. Am I experiencing side effects due to treatment? If so, are they anticipated? If so, are they impacting on overall quality of life/mental health? Is the severity of side effects most important to me?
5. Which ITP treatment do you think will fit best into your life, how much do you think each ITP treatment option will let you carry on doing the activities that are important to you?
6. It is likely that before suggesting a treatment, the clinician will review the following:
   - The extent of your bleeding
   - Your age and lifestyle
   - Other medical conditions and other medication being taken
   - Level of fatigue
   - Tolerance of side effects
   - Your expectations

Questions to consider throughout ITP treatment

Below is a list of questions you may wish to consider throughout ITP treatment:

1. Am I still able to able to undertake the activities that are most important to me?
2. Am I experiencing side effects due to treatment? If so, are they anticipated? If so, are they impacting on overall quality of life/mental health? Is the severity of side effects manageable?
3. Am I satisfied that the treatment is working?
4. Does the frequency and nature of administering treatment still work for me?
Further Information

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About the UK ITP Forum

The UK ITP Forum is a working group of healthcare professionals with a special interest in the care of patients with ITP. The objectives and aims of the forum are:

- To improve care and outcomes for patients with ITP in the UK
- To provide a forum for the interaction of UK healthcare professionals with an interest in ITP
- To develop a network of specialist centres able to provide high quality care and tertiary review
- To advance the education of healthcare professionals and the general public in all aspects of the disease.
- To promote best practice and raise awareness of developments in translational research.
- To encourage collaborative research and trial recruitment into ITP studies.

For more information visit:

www.ukitpforum.org

Further information and patient resources

Below are other websites and and information that patients might find helpful:

- UK Adult ITP Registry
- Current research projects/Clinical Trials
- NICE guideline (NG197): Shared decision making in all healthcare settings
- ITP and Pregnancy
- ITP in Children
- ITP in teenagers and adolescents

Acknowledgments

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The expert ITP Working Group:

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GK Strategy assisted in the development and design of this toolkit.

Patient information available from the ITP Support Association and the UK ITP Forum

About the ITP Support Association

The ITP Support Association is a UK registered charity which aims to promote the general welfare of patients, and the families of patients with immune thrombocytopaenia. The objectives and aims of the forum are:

- To improve care and outcomes for patients with ITP in the UK
- To provide a forum for the interaction of UK healthcare professionals with an interest in ITP
- To develop a network of specialist centres able to provide high quality care and tertiary review
- To advance the education of healthcare professionals and the general public in all aspects of the disease.
- To promote best practice and raise awareness of developments in translational research.
- To encourage collaborative research and trial recruitment into ITP studies.

For more information visit:

www.itpsupport.org.uk
ITP management and care shared decision-making toolkit

Many people write their details in the space below. Knowing who a toolkit belongs to means that it can be returned, if it gets left behind after appointments.

Name:

Named Consultant:

Referral Unit:

Team Members:

Emergency Contact:

NHS Number:

Blood Group:

Weight and Height:

Allergies:

COVID-19 Vaccination Details:

Address and Contact Details:

Additional Notes (editable fields)
A joint initiative between the ITP Support Association and the UK ITP Forum

www.itpsupport.org.uk
www.ukitpforum.org