

# **The UK Paediatric ITP Working Party**

## **UK Childhood ITP Registry (version 3 dated 10.09.2015)**

This is a registry for children with acute and chronic immune thrombocytopenia (ITP), run in collaboration with the intercontinental chronic ITP registry (PARC, Paediatric and Adult intercontinental Registry on Chronic ITP) and the UK adult ITP registry. The primary aim is to relate the long term consequences of a low platelet count to the frequency and severity of bleeding symptoms, and to the requirement for treatment. The Registry is being supported financially by the ITP Support Association.

This document describes the UK Childhood ITP Registry and provides information about procedures for identifying and recruiting patients. The trial coordinators have obtained COREC approval for the Registry. The Registry runs from the website [www.uk-ityp.org](http://www.uk-ityp.org) on an NHS Server with restricted access and has well established back-up and security procedures in place.

This registry involves data collection and Quality of Life assessment only. The study has been adopted by the Children's Research Network. Local centres must however ensure approval from local R&D departments prior to registering children.

Clinicians are asked to read the whole protocol before entering patients into the registry. Centres entering patients for the first time are encouraged to contact one of the trial co-ordinators. Technical advice on how to enter details via the NHS web-server can be obtained from the IT Support Team.

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## Details of Working Party

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## Rationale

The research will establish a prospective registry of children with immune thrombocytopenia (ITP) in the UK and will contribute data to an international registry (PARC, Paediatric and Adult intercontinental Registry on Chronic ITP). The primary aim is to relate the long term consequences of a low platelet count to the frequency and severity of bleeding symptoms, impact on the child and family, and to the requirement for treatment. Adults (people over 18 years of age at presentation) are not included in this application as there is already a registry established for adults in the UK.

ITP is a blood condition characterised by a low platelet count. The platelet count falls because antibodies produced by the patient coat the platelets which are then recognised as abnormal and are removed from the circulation by the normal body scavenging systems. We do not understand why people suddenly start producing antibodies against their own platelets (i.e. the cause of the disorder is not known). Individuals with a very low platelet count are at a higher risk of severe and sometimes life-threatening bleeds. In ITP the risk and severity of bleeding is generally less than predicted by the severity of the low platelet count. In particular, children with very low platelet counts rarely have serious bleeding in this disorder.

The majority of children and some adults will recover from ITP spontaneously and without treatment (within days, weeks or months). However, individuals who have a persistently low platelet count after twelve months from initial diagnosis are defined as having chronic ITP. These people may be at a higher risk of bleeds, particularly if the count remains very low, and may require more aggressive medical treatment or surgical removal of the spleen (splenectomy).

Although ITP has been observed and treated for many years, we know surprisingly little about its causes. The outcome of untreated ITP, optimal treatment of this disorder and the risk of serious bleeds has not been studied systematically.

ITP in childhood occurs at an incidence of 1:25,000 children, about the same as acute leukaemia. In two national surveys, only about 400 new cases per year were recorded in the UK. Often, management of these children did not follow guidelines available in the literature at that time (Bolton–Maggs PHB and Moon I, *Lancet* 1997: 350; 620–623 'Assessment of UK practice for management of acute childhood ITP against published guidelines'). This study demonstrated clearly that most children with very low counts did not have serious bleeding problems, and most recovered spontaneously within a short time. In particular it was not always possible to identify those few individuals at higher risk of life-threatening bleeding based on the platelet count alone.

All treatment is associated with side effects, some of which (such as high dose steroids) may be worse than the disease. In addition, while treatments can effectively raise the platelet count, these drugs do not treat the underlying cause of the low platelet count, which may then fall again when the therapy is stopped. The preferred treatment of individuals with a persistently low platelet count who fail to remit spontaneously or respond to medical treatment may be surgical removal of the spleen (splenectomy). Splenectomy carries its own risks of mortality and morbidity from the surgical procedure itself and from a lifelong higher risk of certain infections which the spleen would normally protect against.

As there is insufficient evidence concerning whom to treat, when to treat and how to treat, little consensus has existed between different expert bodies; North American physicians

have been aggressive in recommendations for therapy (George JN, Woolf SH, Raskob GE, et al.: Idiopathic thrombocytopenic purpura: a practice guideline developed by explicit methods for the American Society of Hematology. *Blood* 1996; 88(1): 3–40), while European physicians are more comfortable treating the majority of children expectantly rather than with interventional therapy (BCSH: Guidelines for the investigation and management of idiopathic thrombocytopenic purpura in adults, children and in pregnancy. *Br J Haematol* 2003; 120(4): 574–96).

Disease registries allow us to build up a more complete picture of the disorder including its natural history and complications. This is particularly helpful for rare disorders where it is very difficult for single centres or even single countries, to accumulate sufficient patients in order to have a clear idea of optimal management. It may be possible to separate patients into distinct subgroups which may help guide future treatment decisions.

## **Study Population**

### Inclusion Criteria

1. All children from the age of 2 months and young people up to the age of 18 years (18<sup>th</sup> birthday) with clinically suspected ITP
2. Primary or secondary ITP
3. Provision of signed, written informed consent from parent and/or guardian
4. Protocol to have received local R&D approval

### Exclusion Criteria

1. Children less than two months or older than 18 years at time of presentation
2. Children with a low platelet count secondary to disorders other than ITP

## **Study Objectives**

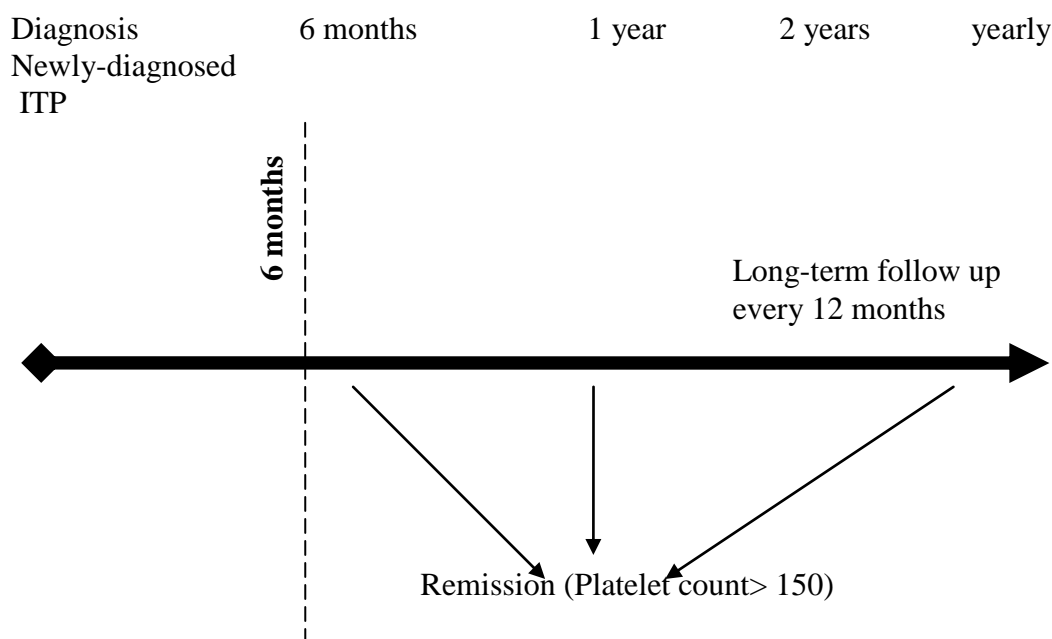
### Primary objectives

1. Establishing a database/data storage facility to relate the long term consequences of a low platelet count to the frequency and severity of bleeding symptoms, and requirement for treatment.

### Secondary Objectives

1. To study the long-term effects of immune thrombocytopenia (ITP).
2. To document the frequency of serious bleeds and the outcome following such bleeds.
3. To document therapies administered to raise platelet count and document response to therapy.
4. To measure the health related quality of life during the disease process
5. To identify information that may be used in future to identify individuals with ITP who are at higher risk of life threatening bleeding, and who require early treatment.
6. To identify information that may be used in future to identify individuals with ITP who are at a low risk of life threatening bleeding and in whom interventional treatment can be safely avoided.
7. To identify other individuals who can teach us more about the outcome of ITP and would be eligible for enrollment in future ethically approved studies.
8. To stimulate scientific research into the development and outcome of ITP

## Study Design



### Data collection and storage

Once patient/parent consent has been obtained, data for collection can be input through the NHS server to the database by the clinician responsible for the patient. Each consultant registering patients is allocated a unique consultant number (UCN). The data entry system generates a unique patient reference number (URN) and the local hospital creates a patient log incorporating this URN so that each patient can be identified locally, but not centrally. The URN enables the local research staff to retrieve case notes for completion of the follow up forms at 6 months, 12 months and annually.

Using the generated URN families will have access to an online or paper questionnaire relating to their quality of life which they are invited to complete.

Data will be stored on a secure electronic database. The server is kept in a locked secure room with limited access. It is configured to use three hard drives with RAID 5 so that in the event of a hard drive failure the failed drive can simply be replaced and rebuilt from the other drives with no loss of data. The server is powered through a UPS (Uninterruptible Power Supply) so that in the event of a power failure it will continue to run. The fileserver

is connected and configured for web access via the trust firewall for access only to the NHS network therefore preventing anyone external to the NHS having access to the web system. In the event of anyone attempting to access the system in an unauthorized way the server will send out notification of this and can then be configured to block access. The server has a tape backup facility which backs up the server each night. Once a week a CD backup copy of all the databases is made and these are stored in a fireproof safe.

If consent has been given for participation in the international study, the data returned to the data manager will also be shared with the study group in Basel. This includes date of birth and patient initials but not postcode or email address. This data will be transferred electronically on a dedicated secure website. The online PARC-ITP database is password protected and data is safeguarded with encryption.

**The sharing of data with PARC is voluntary and does not exclude from the UK registry participation.**

#### Data Collection time points

The data collection form records information such as symptoms, frequency and severity of bleeds, investigations performed, need for hospitalisation and whether treatment was given. Data will be collected at the following time points:

- Presentation
- Six months- in the majority of children the ITP will have spontaneously resolved at this stage. No further data will be collected on children whose ITP has now resolved.
- Twelve months
- Each subsequent year



## **Special Situations**

The registry has highlighted certain situations as being of special interest and which are likely to be informative are likely to teach us more about ITP. In these situations the registry will request additional information from the clinician responsible for the patient.

### Life-threatening bleeds and Intracranial Haemorrhage

Patients with intracranial haemorrhage (ICH) or other life threatening bleeds form a special subgroup in whom additional information will be collected. Intracranial haemorrhage occurs very rarely; there are about 2 cases in the UK per year ('Closing the audit loop – outcome of the second national audit of the management of acute ITP – a change in practice' – Bolton–Maggs PHB and Moon I. Plenary presentation at the RCPCH meeting, April 15th, 2002, York, published abstract no 3847 in Blood 2001; 98 (11) 58b).

While it was thought that the risk of severe bleeds was highest at the time of presentation, this is not so; there are reported cases months to years after diagnosis, and ICH has also occurred in children who have received treatment. The outcome in ICH is not always fatal, particularly where treatment has been rapid. What are the predisposing factors? Do such children have additional conditions such as mild bleeding disorders? Do children with catastrophic bleeding have small congenital blood vessel abnormalities?

More information is required about the incidence, causes, management and outcome of these complications in order to understand it better and to determine whether there is a subgroup of children who can be identified early or who are at particular risk. The ICH and severe haemorrhage registry will collect additional data about children with ITP who suffer ICH or severe haemorrhage.

**ICH definition:** objectively proven (by CT or other imaging, or post-mortem confirmation) bleeding inside the head.

**Severe Haemorrhage definition:** Severe bleeding leading to either hypotensive shock (hypotension, tachycardia and prolonged capillary refill time) or requiring fluid resuscitation (infusion of fluid or blood at a volume of at least 10ml/Kg).

### Pre-operative Therapy

Most children and adults with ITP have mild bleeding symptoms and do not require therapy to raise the platelet count. Therapy is however required to reduce the risk of bleeding for those individuals requiring either invasive dental work or surgery. Guidelines are available for the treatment options for individuals with acute ITP and whom are bleeding; in contrast there are no recommendations for therapy before elective surgery or dental work. The Pre-operative Therapy Registry will collect additional data about children with ITP who receive therapy prior to intended dental extraction or surgery.

### Splenectomy

Splenectomy is a therapeutic option in the management of both children and adults with chronic ITP. It is rarely performed in patients with acute ITP. The spleen is the main organ of antiplatelet antibody production. Moreover the splenic reticuloendothelial system is usually the major site of clearance of antibody coated platelets.

Splenectomy is an accepted and effective treatment of children with chronic ITP, with a lasting response rate of 60% to 88%. There are many unresolved questions about the preoperative and operative management of splenectomy. The practice guidelines issued by haematologists on behalf of the American Society of Haematology noted that there were inadequate data to make evidence-based recommendations on the appropriate indications and timing for splenectomy or when the risks of splenectomy might outweigh its potential benefits. There is a need to assess the long-term response rate of children after splenectomy and to identify predictors of splenectomy failure.

**Consent forms**

Unique Consultant Number:

Patient Initials:

Patient Identification Number for this trial:

**PARENT/PATIENT CONSENT FORM**

(Version 3.0- 10 Sept 2015)

**Title of Project: UK childhood ITP registry**

**Principal Investigator: Dr J Grainger, Royal Manchester Children's Hospital**

**Please initial boxes**

- |   |  |
|---|--|
| <p>1. I confirm that I have read and understand the information sheet(s) dated <input type="text"/> / <input type="text"/> / <input type="text"/> (version <input type="text"/>) for the above study and have had the opportunity to ask questions.</p>   | <div style="border: 1px solid black; background-color: #e0e0e0; padding: 2px; width: 60px; margin: 0 auto;">Please initial</div> |
| <p>2. I understand that my/my child's participation is voluntary and that I am/my child is free to withdraw at any time, without giving any reason, without my/his/her medical care or legal rights being affected.</p>   | <div style="border: 1px solid black; background-color: #e0e0e0; padding: 2px; width: 60px; margin: 0 auto;">Please initial</div> |
| <p>3. I understand that information from my/my child's medical notes will be forwarded on to the secure electronic UK childhood ITP database based in Manchester, UK.</p>   | <div style="border: 1px solid black; background-color: #e0e0e0; padding: 2px; width: 60px; margin: 0 auto;">Please initial</div> |
| <p>4. I agree for information concerning me/my child to be transferred from the UK database to be forwarded electronically to the intercontinental chronic ITP database based in Basel, Switzerland.<br/><i>The sharing of data with PARC is voluntary and does not exclude from the UK registry participation.</i></p> | <div style="border: 1px solid black; background-color: #e0e0e0; padding: 2px; width: 60px; margin: 0 auto;">Please initial</div> |
| <p>5. I agree for my/my child's General Practitioner to be informed about my/his/her entry into this study.</p>   | <div style="border: 1px solid black; background-color: #e0e0e0; padding: 2px; width: 60px; margin: 0 auto;">Please initial</div> |
| <p><i>Information stored in the database may identify children from whom we would like to collect further information.</i></p>  |  |
| <p>6. I agree to be contacted about future ethically approved studies.</p>  | <div style="border: 1px solid black; background-color: #e0e0e0; padding: 2px; width: 60px; margin: 0 auto;">Please initial</div> |

\_\_\_\_\_  
Name of child

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of parent/guardian

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of person taking consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

1 for patient; 1 to be kept with hospital notes

Unique Consultant Number:  
 Patient Initials:  
 Patient Identification Number for this trial:

**PARENT/ PATIENT RE-CONSENT FORM**

(Version 3.0 – 10 Sept 2015)

*As data will continue to be collected over several years a re-consent is required from the child when they are of an appropriate age to have the capacity to understand what is required of them, this is usually between the ages of 10-14.*

**Title of Project: UK childhood ITP registry**

**Principal Investigator: Dr J Grainger, Royal Manchester Children’s Hospital**

**Please initial boxes**

1. I confirm that I have read and understand the information sheet(s) dated  /  /  (version ) for the above study and have had the opportunity to ask questions. Please initial
  
2. I understand that my continued participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. Please initial
  
3. I understand that information from my medical notes will be forwarded on to the secure electronic UK Childhood ITP database based in Manchester, UK. Please initial
  
4. I agree for information concerning me to be transferred from the UK database to be forwarded electronically to the intercontinental chronic ITP database based in Basel, Switzerland. *The sharing of data with PARC is voluntary and does not exclude from the UK registry participation.* Please initial
  
5. I agree for my General Practitioner to be informed about my entry into this study. Please initial
  
- Information stored in the database may identify children from whom we would like to collect further information.*
6. I agree to be contacted about future ethically approved studies. Please initial

Name of child	Date	Signature
Name of parent/guardian	Date	Signature
Name of person taking consent	Date	Signature

1 for patient; 1 to be kept with hospital notes

## **Parent and patient information Sheets**

**TO BE PRINTED ON LOCAL HEADED PAPER**

United Kingdom Childhood ITP Registry

### **INFORMATION FOR PARENTS**

**(Version 3.0, 10 Sep 2015)**

We are asking you to consider the possibility of allowing information about your child to be included in an information registry. In doing this we are trying to gain more information about the medical condition Immune Thrombocytopenia (ITP).

Before you decide it is important for you to understand why the research is being done and what is involved. Please take time to read the following information carefully and discuss it with friends, relatives, doctors and nurses if you wish. Ask us if there is anything that is not clear or if you would like more information. Take the time to decide whether or not you wish your child to take part.

#### **1. What is the purpose of the registry?**

Immune thrombocytopenia (ITP) is a blood condition characterised by a low platelet count. The platelet count drops because antibodies produced by the patient coat the platelets which are then recognised as abnormal and are removed from the blood stream by the normal body protection systems. There are many aspects of ITP that we do not fully understand, for instance why do people suddenly start producing antibodies against their own platelets, why do children with very low platelet counts rarely have serious bleeding, why some children get better quickly and others have a more long term disorder. We would also like to know more about the very best treatment for children with ITP.

To help us answer these questions we want to collect information about children with ITP in the UK in a systematic way to create a collection of information (or registry). This will form part of an international registry (PARC, Paediatric and Adult intercontinental Registry on Chronic ITP).

The main aims of this project are to try and understand when and why children with a low platelet count bleed, when and why there is a need for treatment and how having ITP impacts on the quality of life on the child and family.

## **2. Why has my child been chosen?**

All children under the age of 18 years who present to hospital in the UK with ITP will be eligible to take part in this project.

## **3. Does my child have to take part?**

No. Participation in the project is entirely voluntary. If you agree to your child taking part and then later change your mind, you are still free to withdraw at any time without giving a reason. This will not affect the standard of care received by your child.

## **4. What do I have to do?**

If you agree for your child to take part in this project we will need you to sign a consent form. You will be given a copy of the consent form and this information sheet to keep.

## **5. What will happen if my child takes part?**

This information sheet has been sent out from the study headquarters (based at Royal Manchester Children's Hospital). A doctor looking after your child in your hospital will discuss the project with you and you will also be able to speak with one of the chief researchers by telephone if you have any additional questions before signing the consent form. If you consent to participate your doctor will read your child's medical notes and complete a form about your child's condition including symptoms, how often they bleed and what treatment is required. These forms are returned to the central data manager and stored securely. If you agree this information will also be shared with the international PARC study group (head quarters in Basel, Switzerland) by secure electronic transfer.

Six months after your child first developed ITP further information will be collected by means of a second form again filled in by your local hospital doctor. However at this stage the majority of children will have recovered fully. The registry will continue to follow up only those with ITP that does not get better quickly (about 20% of patients). Information will then be collected every twelve months until either the ITP gets better or the project closes.

The database may pick out individual children whose bleeding pattern or clinical course may teach us more about ITP. Such individuals may be approached regarding other ethically approved studies.

If your child is over the age of 2 years, you will also be asked to complete a 10 minute online/paper questionnaire regarding how ITP has affected your child's daily life . If your child is 7 years or older we will also ask them to complete the same questionnaire on their own. We will ask you to complete these questionnaires within the first two weeks of the ITP been diagnosed, at 6 weeks, at 6 months and then if the ITP is persisting again on a yearly basis until the ITP goes away.

**6. Are there any disadvantages or risks involved in my child's participation in the project?**

No.

**7. What are the possible benefits of taking part?**

The information we obtain will not be of direct benefit to your child at the moment but may improve the way we treat other children with ITP in the future. However if your child has ITP for a long time information gained from this project may help their future treatment.

**8. Will my child's participation in this study be kept confidential?**

Your child will be allocated a unique case number that will be kept by your hospital doctor. This will be used to identify the information sent to the ITP registry co-ordinators. The ITP registry co-ordinators will not know your child's name.

The database will record the following personal information about your child:

- Date of Birth - this to enable accurate record of your child's age over time
- Post Code- this is so we can identify where cases appear so we can identify patterns which may provide useful information to better understand how ITP develops
- Parental email address - this is so we can email you a unique link for the quality of life forms
- Initials - occasionally ITP can recur later in life. The use of initials and date of birth enable us to identify when a patient has previously been entered onto the registry. Some patients may also be treated at a local hospital and also at a specialist hospital so we can also identify duplicate entry of details.

### **9. What will happen to the results of the study?**

Information from the registry will be stored electronically on a secure database. Analysis will be carried every six to twelve months. The results will be published in medical journals and possibly used to modify future treatment. Information from the database will be fed back to families via the ITP support association. Your child will not be identified in any report or publication.

### **10. Who is organising and funding the research?**

This project is being undertaken by The UK Paediatric ITP Working Party led by Dr. John Grainger, Consultant Paediatric Haematologist in the Manchester Children's Hospital. The study is funded by the ITP Patient Support Organisation. There will be no payments to researchers for conducting the project.

### **11. What if I have any concerns?**

If you have any concerns or other questions about this project or the way it has been carried out, you should contact a member of the working party

### **12. Contact for further information**

If you require any further information please contact a member of the working party:

<b>Name</b>	<b>Hospital</b>	<b>Telephone No.</b>
Dr John Grainger	Royal Manchester Children's	0161 701 8416

Thank you for reading this information sheet.



United Kingdom Childhood ITP Registry

**INFORMATION FOR PATIENTS 14-18yrs (ENGLAND, WALES, SCOTLAND AND N.IRELAND)**

**(Version 3.0, 10 Sep 2015)**

We are asking you to consider the possibility of allowing information about yourself to be included in an information registry. In doing this we are trying to gain more information about the medical condition Immune Thrombocytopenia (ITP).

Although we have to ask your parents permission it is important for you to understand why the research is being done and what is involved. Please take time to read the following information carefully and discuss it with your parents, friends, relatives, doctors and nurses if you wish. Ask us if there is anything that is not clear or if you would like more information. Take the time to decide whether or not you wish to take part.

**1. What is the purpose of the registry?**

Immune thrombocytopenia (ITP) is a blood condition where the main problem is a low platelet count. The platelet count drops because antibodies produced by the patient coat the platelets which are then recognised as abnormal and are removed from the blood stream by the normal body protection systems. There are many aspects of ITP that we do not fully understand, for instance why do people suddenly start producing antibodies against their own platelets, why do young people with very low platelet counts rarely have serious bleeding, why some young people get better quickly and others have a more long term disorder. We would also like to know more about the very best treatment for young people with ITP.

To help us answer these questions we would like to collect information about young people with ITP in the UK in an organised way to create a collection of information (or registry).

This will form part of an international registry (PARC, Paediatric and Adult intercontinental Registry on Chronic ITP).

The main aims of this project are to try and understand how the low platelet count relates to how often and how badly children bleed, how it relates to the need for treatment and how it impacts on the quality of life on the child and family.

## **2. Why have I been chosen?**

All children under the age of 18 years who present to hospital in the UK with ITP will be eligible to take part in this project.

## **3. Do I have to take part?**

No. Participation in the project is entirely voluntary. If you agree to take part and then later change your mind, you are still free to withdraw at any time without giving a reason. This will not affect the standard of care you receive.

## **4. What do I have to do?**

We have to ask your parents' permission for you to take part and will need them to sign a consent form, but it is important that you understand what this project is about and are happy to take part too. You may sign the consent form too if you wish. You will be given a copy of the consent form and this information sheet to keep.

## **5. What will happen if I take part?**

This information sheet has been sent out from a central information controller for this project (based in Manchester). Your doctor should also discuss the project further with you. You can also speak to one of the chief researchers by telephone if any of you have any outstanding questions before signing the consent form. If you consent to the project your doctor will read your medical notes and complete a form about your condition including symptoms, how often you bleed and what treatment is required. These forms are returned to the central information controller and stored securely. If you agree this information will be shared with the international PARC study group in Basel, Switzerland. Six months after you first developed ITP further information will be collected by means of a second form again filled in by your local hospital doctor. However at this stage the majority of young people will have recovered fully. The registry will continue to follow up only those with

ITP that does not get better quickly (about 20% of people). Information will then be collected every twelve months until either the ITP gets better or the project closes.

The database may pick out individuals whose bleeding pattern or clinical course may teach us more about ITP. Such individuals may be approached regarding other ethically approved studies.

**6. Are there any disadvantages or risks involved in my participation in the project?**

No.

**7. What are the possible benefits of taking part?**

The information we gain will not be of direct benefit to you at the moment but may improve the way we treat other children with ITP in the future. However if you have ITP for a long time information gained from this project may help your treatment.

**8. Will my taking part in this study be kept confidential?**

You will be allocated a unique case number that will be kept by your hospital doctor. This will be used to identify the information sent to the information co-ordinators. They will not be able to know your name.

The research team will know your initials, date of birth and post code. These details are stored to help us with our research. We also collect a parent's email address so we can email access to the quality of life forms for you to complete.

**9. What will happen to the results of the study?**

Information from the registry will be kept for twenty years. Analysis will be carried yearly. The results will be published in medical journals and possibly used to modify future treatment. You will not be identified in any report or publication.

**10. Who is organising and funding the research?**

This project is being undertaken by The UK Paediatric ITP Working Party led by Dr. John Grainger, Consultant Paediatric Haematologist in the Manchester Children's Hospital and locally by [name, department]. The study is funded by the ITP Patient Support Organisation. There will be no payments to researchers for conducting the project.

**11. What if I have any concerns?**

If you have any worries or concerns about anything we have talked about in this information sheet the doctors or nurses at your clinic would be happy to talk with you about them or you may contact the hospital/PCT/Health Authority complaints department (insert local contact details).

**12. Contact for further information**

If you require any further information please contact the consultant who is looking after you.

Thank you for reading this information sheet.

United Kingdom Childhood ITP Registry

**INFORMATION FOR PATIENTS 12-14yrs**

**(Version 3.0, 10 Sep 2015)**

We would like to try and find out more about your condition, Immune Thrombocytopenia. We are asking your parents to consider allowing information about you to be recorded in an information registry.

Before they decide it is important for you to understand why this is being done and what will happen. Please take time to read the following information carefully and discuss it with your parents, friends, relatives, doctors and nurses if you wish. Ask us if there is anything that is worrying you or you do not understand, and think about if you would like to take part.

**1. What is the purpose of the registry?**

Immune thrombocytopenia (ITP) is a blood condition which means you don't have a lot of platelets. Platelets are in the blood to help us stop bleeding if we cut ourselves or fall. There are many things about ITP that we do not fully understand, for example why do people with very low platelet counts rarely have big bleeds, why some people get better quickly and others don't. We would also like to know more about the very best treatment for children/ young people with ITP.

To help us answer these questions we would like to collect information about children and young people with ITP in the UK.

Mainly we want to try and understand if the low platelet count can show us how often and how badly children bleed, how it should be treated and how all of this affects you and your family.

## **2. Why have I been chosen?**

All children under the age of 18 years who come to hospital in the UK with ITP will be asked to take part in this project.

## **3. Do I have to take part?**

No. You can say no and that is fine. No one will be upset or angry if you and your family say no. If you do say yes and then later change your mind, you can stop at any time without giving a reason. This will not change how you are treated.

## **4. What do I have to do?**

We have to ask your parents' permission for you to take part and will need them to sign a consent form, but it is important that you understand what this project is about and are happy to take part too. You may also sign the consent form if you wish. You will be given a copy of the consent form and this information sheet to keep.

## **5. What will happen if I take part?**

If you decide to take part then after your parents have signed a consent form your doctor will fill in a form about your ITP telling how often you have had a bleed, and what treatment you have needed. Your name will not be on the form so no-one will know it is about you. The information will be safely stored and used in the U.K. and also in Switzerland. Six months after you first developed ITP more information will be collected on a second form filled in by your doctor. However at this time most children/young people will have recovered fully. The registry will only carry on following those who do not get better quickly. Information will then be collected every twelve months until either the ITP gets better or the project stops.

## **6. Are there any disadvantages or risks involved in my participation in the project?**

No.

## **7. What are the possible benefits of taking part?**

The information we gather will not help you at the moment but may make things better for the way we treat other children with ITP in the future. However if you have ITP for a long time information gathered from this project may help your future treatment.

**8. What will happen to the results of the study?**

Information gathered will be stored securely. Every six to twelve months we will review all the information we have. The results will be published in medical journals and may be used to change treatment in the future. Your name will not be in any report or publication.

**9. What if I have any concerns?**

If you have any worries or concerns about anything we have talked about in this information sheet the doctors or nurses at your clinic would be happy to talk with you about them.

Thank you for reading this information sheet.

**INFORMATION FOR PATIENTS 10-12yrs**

**(Version 3.0, 10 Sep 2015)**

You have something wrong with your blood that can make you bleed or bruise this is called ITP. We would like to know more about ITP and are asking you and your parents if we can collect information about your ITP.

Before you they decide it is important for you to understand why this is being done and what will happen. Please discuss it with your parents, doctors and nurses if you wish. Ask us if there is anything that is worrying you or you do not understand.

**1. Why are you collecting this information?**

There are many things about ITP that we do not understand, for example why do some children with ITP bleed and some don't. To help us answer these questions we would like to collect information about all children and young people with ITP in the UK.

**2. Why have I been chosen?**

All children under the age of 18 years who come to hospital in the UK with ITP will be asked to take part in this project.

**3. Do I have to take part?**

No. You can say no and that is fine. No one will be upset or angry if you and your family say no. If you do say yes and then later change your mind, you are can stop at any time without giving a reason. This will not change how you are treated. When you are older we will ask you again to check that you still feel ok for us to continue collecting information about you.



#### **4. What do I have to do?**

We have to ask your parents' permission for you to take part and will need them to sign a form, but it is important that you are happy to take part too. You may also sign the consent form if you wish.

#### **5. What will happen if I take part?**

If you decide to take part then your doctor will fill in a form about your ITP telling how often you have had a bleed, and what treatment you have needed. Your name will not be on the form so no-one will know it is about you.

Six months after you first developed ITP more information will be collected on a second form filled in by your doctor. However at this time most children/young people will have recovered fully. We will only carry on collecting information about those children who do not get better quickly.

#### **6. Might anything about this upset me?**

No.

#### **7. Will this help me?**

The information we gather will not help you but may make things better for the way we treat other children with ITP in the future.

#### **8. What if I have any worries or questions?**

If you have any worries or concerns about anything we have talked about in this information sheet the doctors or nurses would be happy to talk with you about them.

Thank you for reading this information sheet.

**INFORMATION SHEET TO BE READ TO PATIENTS UNDER 10  
YEARS.**

**(Version 3.0, 10 Sep 2015)**

You have something wrong with your blood that can make you bleed or bruise this is called ITP. Other children get ITP too! Sometimes they have it a long time and sometimes it goes away quickly.

The doctors know a lot about ITP, but they would like to find out more so they can get better at looking after children who have it.

To find out more about it we need to ask questions to all the doctors looking after children with ITP. We can then collect together all the answers and look at them carefully.

Before we can ask the doctors any questions about you we have to ask your mum and dad's permission to make sure that they are happy about it.

We will keep on asking the doctors questions about you until your ITP goes away, or we think we have got enough information.

If you want to ask us anything that you are not sure about then we will be very happy to talk to you.

If you or your mum and dad don't want to take part then this is OK and no one will be upset.

**Thank you.**

United Kingdom Childhood ITP Registry

(Version 3.0, 10 Sep 2015)

## **INFORMATION FOR GENERAL PRACTITIONERS, PAEDIATRICIANS AND HAEMATOLOGISTS**

Chronic ITP in children is an uncommon disorder, and there still remain many uncertainties about its treatment and outcome. The few ITP trials to date concentrate on ITP in adults, and few centres are large enough to allow single-centre registries to be set up. The previous paediatric audits have collected data over a short period of time and were not designed for longer term analyses. By collecting fairly simple demographic and clinical data we will be able to follow patients over time, and learn more about the factors that determine clinical outcome. It will be particularly helpful to identify factors that predict which children presenting with ITP will develop chronic ITP, and the outcome in children who are treated and those who are observed. Although this study may not have an immediate impact on the individual management of your patients, we hope that it will benefit children with ITP in the future.

The Registry is being generously financially supported by the ITP Support Group. The Royal College of Paediatricians and British Society of Haematology have written in support of the study.

### **Design of the Registry**

Paediatricians and haematologists will be asked to notify children up to the age of 18 years with newly diagnosed ITP. Age-appropriate patient information sheets and consent forms will be distributed. Consent for participation in the Registry will be obtained locally. No additional investigations or samples will be required.

Data for the registry can be entered directly via the registry website on the NHS secure server. All data will be identified via a unique patient number assigned to each new patient.

. The Registry server is held securely with restricted access, and with established back-up and security procedures in place.

Initial presenting data will be collected within one year of diagnosis. Further data will be requested at six months to collect data on symptoms, investigation and the need for treatment. Children whose ITP has resolved by six months will not be followed further. Children with chronic ITP (defined as persistently low platelet count at six months after presentation) will be followed annually, until resolution of their ITP or closure of the study.

**Data analysis: link with international PARC registry**

The UK Registry will contribute anonymised data by secure electronic transfer to an international registry, the Paediatric and Adult intercontinental Registry on Chronic ITP (PARC), which is centered in Basel, Switzerland. In this way data can be analysed from a much higher number of children with chronic ITP, which will increase the likelihood of obtaining useful information.

Your participation in this Registry will be important to ensure that the data collected will truly represent the incidence and outcome of childhood ITP in the UK. Please do contact any of the investigators listed below if you would like further information. You will be kept informed of the progress of the Registry.

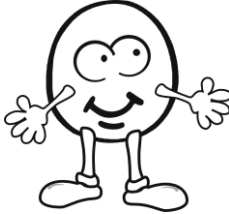
<b>Name</b>	<b>Hospital</b>	<b>Telephone No.</b>
Dr John Grainger	Royal Manchester Children's	0161 701 8416

Your initials: \_\_\_\_\_

Your DOB: \_\_\_\_\_

Study ID: \_\_\_\_\_

Date: \_\_\_\_\_



**Time points for completion:**

- within the first 2 weeks of diagnosis
- at 6 weeks
- at 6 months
- yearly (if ITP persisting)

# KIDS' ITP TOOLS

(UK - English)

Child Self-Report of Quality of Life

## INSTRUCTIONS

On the next two pages, there are questions that ask you **about this past week**. We know that ITP has mattered to you from when you first came to hospital, but **for this study, we really need you to focus on what you thought about and did over the past week**. You may have done things at home, at the hospital, at school and with your friends. Record your answer by putting a tick (✓) in the box of the most correct choice.

**It is important that you answer all questions about this past week.**

**What do the answers mean?**

### Answers

### Meaning

Never	=	none of the time
Rarely	=	almost none of the time
Sometimes	=	once in a while
Often	=	almost all of the time
Always	=	all of the time

In general, over the past week ...	Never	Rarely	Sometimes	Often	Always
1. I felt poorly...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I had a headache...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I felt tired...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I felt upset (sad or angry)...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I felt cranky (bad tempered or moody)...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I felt anxious (worried or nervous or afraid)...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I was more hungry than usual...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

In general, over the past week ...	Never	Rarely	Sometimes	Often	Always
8. I was bothered that I could not do things with my friends...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I was bothered because I could not do the activities I like...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. I was more frustrated with my parents than usual...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. I was bothered by how much my parents watched me...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. I was bothered because I did not know enough about ITP...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. I was bothered that I didn't know how long my ITP would last...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. I was bothered that I could not do anything to get better...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Over the past week ...	Never	Rarely	Sometimes	Often	Always
15. I worried about my platelet count...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. I worried about my ITP getting worse...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. I worried about having a more serious disease...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please Note: the next set of questions have an **additional** answer.

Over the past week ...	Never	Rarely	Sometimes	Often	Always
18. I was bothered by my bruises...  or <input type="checkbox"/> I did not have any bruises in the past week.	<i>Never</i> <input type="checkbox"/>	<i>Rarely</i> <input type="checkbox"/>	<i>Sometimes</i> <input type="checkbox"/>	<i>Often</i> <input type="checkbox"/>	<i>Always</i> <input type="checkbox"/>
19. I was bothered by changes in how I looked...  or <input type="checkbox"/> I did not have any changes in how I looked in the past week.	<i>Never</i> <input type="checkbox"/>	<i>Rarely</i> <input type="checkbox"/>	<i>Sometimes</i> <input type="checkbox"/>	<i>Often</i> <input type="checkbox"/>	<i>Always</i> <input type="checkbox"/>
20. Having blood taken bothered me...  or <input type="checkbox"/> I did not have blood taken in the past week.	<i>Never</i> <input type="checkbox"/>	<i>Rarely</i> <input type="checkbox"/>	<i>Sometimes</i> <input type="checkbox"/>	<i>Often</i> <input type="checkbox"/>	<i>Always</i> <input type="checkbox"/>
21. Staying overnight in the hospital bothered me...  or <input type="checkbox"/> I did not stay overnight in hospital in the past week.	<i>Never</i> <input type="checkbox"/>	<i>Rarely</i> <input type="checkbox"/>	<i>Sometimes</i> <input type="checkbox"/>	<i>Often</i> <input type="checkbox"/>	<i>Always</i> <input type="checkbox"/>
22. Going to clinic bothered me...  or <input type="checkbox"/> I did not go to clinic in the past week.	<i>Never</i> <input type="checkbox"/>	<i>Rarely</i> <input type="checkbox"/>	<i>Sometimes</i> <input type="checkbox"/>	<i>Often</i> <input type="checkbox"/>	<i>Always</i> <input type="checkbox"/>
23. Having my treatment through a drip bothered me...  or <input type="checkbox"/> I did not have treatment through a drip in the past week.	<i>Never</i> <input type="checkbox"/>	<i>Rarely</i> <input type="checkbox"/>	<i>Sometimes</i> <input type="checkbox"/>	<i>Often</i> <input type="checkbox"/>	<i>Always</i> <input type="checkbox"/>
24. Taking medicine by mouth bothered me...  or <input type="checkbox"/> I did not take medicine by mouth in the past week.	<i>Never</i> <input type="checkbox"/>	<i>Rarely</i> <input type="checkbox"/>	<i>Sometimes</i> <input type="checkbox"/>	<i>Often</i> <input type="checkbox"/>	<i>Always</i> <input type="checkbox"/>
25. I was bothered by missing school...  or <input type="checkbox"/> I did not miss school in the past week.	<i>Never</i> <input type="checkbox"/>	<i>Rarely</i> <input type="checkbox"/>	<i>Sometimes</i> <input type="checkbox"/>	<i>Often</i> <input type="checkbox"/>	<i>Always</i> <input type="checkbox"/>
26. I worried that I might need to have a bone marrow test...	<i>Never</i> <input type="checkbox"/>	<i>Rarely</i> <input type="checkbox"/>	<i>Sometimes</i> <input type="checkbox"/>	<i>Often</i> <input type="checkbox"/>	<i>Always</i> <input type="checkbox"/>
27. Have you ever had a bone marrow test?	<input type="checkbox"/> yes	<input type="checkbox"/> no			

**Was there anything else that bothered you?**

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**Thank you!**

**If you have any questions about these forms, please talk to the person who gave them to you. If you have any questions about your ITP, please talk to your doctor or nurse.**

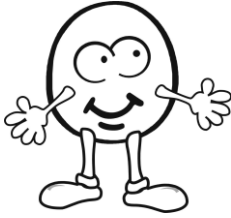
**Please return this form to:**

**Stephanie Farrell  
UK Paediatric ITP Registry Data Manager  
Immunology, CSB3, Offices 10 & 11  
3rd floor Manchester Royal Infirmary  
Oxford Road, Manchester  
M13 9WL, UK**



Your child's initials: \_\_\_\_\_ Your child's DOB: \_\_\_\_\_

Study ID: \_\_\_\_\_ Date: \_\_\_\_\_



**Time points for completion:**

- within the first 2 weeks of diagnosis
- at 6 weeks
- at 6 months
- yearly (if ITP persisting)

# KIDS' ITP TOOLS

(UK – English)

Parent Report of Child's Quality of Life

## INSTRUCTIONS

For this questionnaire, we are asking; **How much of a problem has this been for your child over the past week?** Mark the answers that you think your child would select. We know that ITP has had an impact on your child since diagnosis, but for this study, we need you to **focus on what your child would have answered about the past week.** Record the answer by putting a tick (✓) in the box of the most correct choice. **Answer in general, don't worry if an answer is not because of ITP.**

**It is important that you answer all questions about this past week.**

### What do the answers mean?

<u>Answers</u>		<i>Meaning</i>
Never	=	none of the time
Rarely	=	almost none of the time
Sometimes	=	once in a while
Often	=	almost all of the time
Always	=	all of the time

**Note: You may provide other comments about your child's ITP at the end of the questionnaire**

**Please answer as your child would.**

In general, over the past week ...	Never	Rarely	Sometimes	Often	Always
1. My child felt poorly...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. My child had a headache...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. My child felt tired...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. My child felt upset (sad or angry)...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. My child felt cranky...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. My child felt anxious (worried, nervous or afraid)...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. My child was more hungry than usual...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

In general, over the past week ...	Never	Rarely	Sometimes	Often	Always
8. My child was bothered that she/he could not do things with friends...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. My child was bothered because he/she could not do the activities he/she likes...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. My child was more frustrated with me than usual...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. My child was bothered by how much I watched her/him...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. My child was bothered because she/he did not know enough about ITP...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. My child was bothered that he/she didn't know how long the ITP would last...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. My child was bothered that she/he could not do anything to get better...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

In general, over the past week ...	Never	Rarely	Sometimes	Often	Always
15. My child worried about his/her platelet count...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. My child worried about the ITP getting worse...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. My child worried about having a more serious disease...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please Note: the next set of questions have an **additional** answer.

In general, over the past week ...	Never	Rarely	Sometimes	Often	Always
18. My child was bothered by her/his bruises...	<i>Never</i>	<i>Rarely</i>	<i>Sometimes</i>	<i>Often</i>	<i>Always</i>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
or <input type="checkbox"/> My child did not have any bruises in the past week.					
19. My child was bothered by changes in how he/she looked...	<i>Never</i>	<i>Rarely</i>	<i>Sometimes</i>	<i>Often</i>	<i>Always</i>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
or <input type="checkbox"/> My child did not have any changes in how he/she looked in the past week					
20. Having blood taken bothered my child...	<i>Never</i>	<i>Rarely</i>	<i>Sometimes</i>	<i>Often</i>	<i>Always</i>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
or <input type="checkbox"/> My child did not have blood taken in the past week.					
21. Staying overnight in the hospital bothered my child...	<i>Never</i>	<i>Rarely</i>	<i>Sometimes</i>	<i>Often</i>	<i>Always</i>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
or <input type="checkbox"/> My child did not stay overnight in hospital in the past week.					
22. Going to clinic bothered my child...	<i>Never</i>	<i>Rarely</i>	<i>Sometimes</i>	<i>Often</i>	<i>Always</i>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
or <input type="checkbox"/> My child did not go to clinic in the past week.					
23. Having treatment through a drip bothered my child...	<i>Never</i>	<i>Rarely</i>	<i>Sometimes</i>	<i>Often</i>	<i>Always</i>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
or <input type="checkbox"/> My child did not have treatment through a drip in the past week.					
24. Taking medicine by mouth bothered my child...	<i>Never</i>	<i>Rarely</i>	<i>Sometimes</i>	<i>Often</i>	<i>Always</i>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
or <input type="checkbox"/> My child did not take medicine by mouth in the past week.					
25. My child was bothered by missing school...	<i>Never</i>	<i>Rarely</i>	<i>Sometimes</i>	<i>Often</i>	<i>Always</i>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
or <input type="checkbox"/> My child did not miss any school in the past week.					
26. My child worried that she/he might need to have a bone marrow test...	<i>Never</i>	<i>Rarely</i>	<i>Sometimes</i>	<i>Often</i>	<i>Always</i>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. Has your child ever had a bone marrow test?	<input type="checkbox"/> yes	<input type="checkbox"/> no			

**Was there anything else that bothered your child?**

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**Thank you!**

**If you have any questions about these forms, please talk to the person who gave them to you. If you have any questions about your child's ITP, please talk to your child's doctor or nurse.**

**Please return this form to:**

**Stephanie Farrell  
UK Paediatric ITP Registry Data Manager  
Immunology, CSB3, Offices 10 & 11  
3rd floor Manchester Royal Infirmary  
Oxford Road, Manchester  
M13 9WL, UK**