Thalassaemia International Federation (TIF)

Information for TIF Collaborating Centres for Haemoglobinopathies Educational Programmes

Nicosia, Cyprus | 2024

TABLE OF CONTENTS

EXECUTIVE SUMMARY

This document outlines the process for centres partnering with Thalassaemia International Federation (TIF) to host an educational programme, including the Renzo Galanello Fellowship Programme. This process consists of two phases. Initially, a center approached by TIF, and which expresses interest in hosting an educational programme, including the Renzo Galanello Fellowship Programme, must first become a TIF Collaborating Center. This involves reviewing this document, completing an initial checklist, and obtaining the necessary permissions from national health authorities and/or relevant competent national organisations of the country. Upon completion of these steps, an onsite visit by TIF will occur, leading to the signing of a memorandum of agreement enabling the initiation of the fellowship programme at the centre. Lastly, this document includes information on the current Renzo Galanello Fellowship Programme.

INTRODUCTION

The Thalassaemia International Federation (TIF) was founded with the vision and mission to ensure the equal access to optimum care for all thalassaemia and haemoglobinopathy patients around the world. The quality of care is central to achieving the desired patient outcomes of reduced morbidity, good quality of life and long survival. Through its extensive educational programme, which includes a series of educational publications as well as educational events, conferences, fellowships, and workshops, TIF aims to spread awareness, knowledge, and share best practices, targeting at promoting effective national control programmes across the world.

The Renzo Galanello Fellowship Programme is one of TIF's educational initiatives in honour of the late Professor Renzo Galanello pioneer in the field of thalassaemia research and management, which was initially developed in 2013 and is offered to physicians, specialists in the field of haematology, paediatrics, or internal medicine. As of 2015, the programme is undertaken by the Joint Red Cell Unit, Haematology Department of the University College London, NHS Foundation Trust in London, UK.

TIF is aware that in many countries there is a shortage and even more importantly lack of trained medical staff in haemoglobinopathies. As a result, healthcare of haemoglobinopathy patients is often suboptimal and even rudimentary. This deficiency partly stems from a general lack of interest in non-malignant haematological disorders within the haematology circles. Additionally, in some regions, these disorders are considered rare and are not prioritised or integrated into national strategies or programmes. Improving knowledge of holistic care in thalassaemia and sickle cell disease, has been a priority for TIF since its establishment in 1986, and this need knows no geographical boundaries.

Consequently, TIF aims to extend its fellowship programme to other countries where thalassaemia centres offer high-quality, multidisciplinary care to patients. To ensure that potential fellows receive exemplary training, TIF first needs to establish collaboration with high-calibre centres. In the next pages you will find the phases required for the establishment and initiation of a Renzo Galanello Fellowship Programme as well as information about the operation and current fellowship program.

PHASES PRIOR TO THE INITIATION OF AN EDUCATIONAL PPORGRAMME, INCLUDING RENZO GALANELLO FELLOWSHIP PROGRAMME

1. **Phase A:**
   TIF Collaborating Centre to:
   a. Review this document.
   b. *Complete center assessment checklist* (see "Phase A" section in this document)
   c. Return the completed "Phase A: Assessment Checklist" to TIF at thalassaemia-kp@thalassaemia.org.cy

2. **Phase B:**
   Thalassaemia International Federation to:
   a. Carry out an onsite visit and meet with medical team and management of the centre/ hospital. Phase B Checklist to be completed – see Annex II.
   b. Inform the Ministry of Health (or other competent national authorities) of TIF's efforts in the country.

   Prior to signing a memorandum of agreement, we need to confirm that:
   a. The center and you as the leader/coordinator has received the necessary, for you and your center/clinic, permission from the relevant competent authorities to become a TIF collaborating center. TIF is at your disposal for the provision of an official letter should the need arises.
   b. Upon agreement and relevant permissions are obtained, an educational programme such as Renzo Galanello Fellowship can be organised and held at the collaborating centre.

3. **NB:**
   The center will not charge the training of any doctor coming from the country or from any country of the region (and beyond). TIF will undertake to cover the cost partly or whole of:
   a. Traveling expenses of the trainee.
   b. Accommodation of 10 nights for the trainee.
   c. Any administrative fees to the hospital of no more than 500USD for the period of 10-15 days of training.

The ultimate vision of the above process is creating a network of TIF collaborating centres where:

1. Healthcare professionals can be trained on the prevention and management of thalassaemia and SCD, based on the latest evidence-based practices.

TIF Collaborating Centres for Haemoglobinopathies

THE NEED FOR TIF COLLABORATING CENTRES

There are in many countries in which centres are labelled “Thalassaemia Centres” either nationally assigned, EU assigned, or self-assigned. These vary considerably in their expertise, their services, the number of patients and the level of support they receive from national health authorities. Very few, however, have attained an international accreditation and recognition. Patient outcomes, which constitute the evidencing of the quality of services provided in a country are very rarely recorded, including survivorship, age distribution, morbidity, and mortality rates. TIF aims to offer the Renzo Galanello Fellowship at centres where quality care is provided to patients based on well-defined and internationally accepted quality standards that ensure a comprehensive multi-disciplinary approach to patients’ needs.

The significantly improved health and quality of life resulting from improved care and services provided to patients with thalassaemia and other haemoglobinopathies have demonstrated in recent years through survival studies conducted in Cyprus, Greece, Italy, UK, and some other, mainly Western countries. Consequently, there is a growing need for the establishment of collaborating centres in various countries where training can be facilitated by experienced medical experts. This collaborative approach is considered one of the most effective management strategies for successfully advancing the patient care. Moreover, these collaborating centres can serve as educational hubs, showcasing their organisational methods to national and international healthcare professionals and potential thalassaemia centres thereby ensuring consistent quality of care worldwide.

QUALITY STANDARDS

The developed TIF Quality Standards are based on the general principles already developed by the following organisations:

- The Joint Commission International (JCI): “Survey process Guide for Ambulatory Care (4th Edition, 2019)
- European Union Committee of Experts on Rare Diseases (EUCERD): Quality Criteria for Centres of Expertise for Rare Diseases in Member States (2011) and EUCERD recommendations on Rare Disease European Networks (2013)
- Guidelines for Good Clinical Practice
- US Institute of Medicine: Quality Improvement
- US Department of Health and Human Services, Health Resources and Service Administration: Quality Improvement
- UK NHS, Peer review of health Services for People with Haemoglobin Disorders: (2015 Review)
- TIF “Guidelines for the management of transfusion dependent thalassaemia” 4th edition 2021
- TIF “Guidelines for the management of non-transfusion dependent thalassaemia” 2023
- Specific standards, such as the “International Collaboration for Transfusion Medicine (ICTMG): Red blood cell specifications for patients with haemoglobinopathies: a systematic review and guideline” 2017
- ENERCA White Book
- European Guidelines for the certification of Haemophilia Centres EUHANET 2013.
- Current literature reviews

The criterion for recognising any centre a TIF's collaborating centre is the quality of services, and not just the availability of various technical components necessary for thalassaemia care. Quality care involves patient-centred care. It includes following national or international evidence-based guidelines, which allow for good patient outcomes. The services provided by TIF collaborating centres should be based on the elements, components and programmes used by centres with successful outcomes on the European standards for reference centres, and including:

1. The capacity to provide **expert diagnosis** of the disease as well as its long-term complications.

2. The capacity to provide **expert case management**, including a multidisciplinary approach and psychosocial support. These requirements imply **experienced healthcare personnel** in adequate numbers to ensure continuity of care.

3. Health care workers should be in a structured environment with **clearly defined roles and hierarchy.**

4. Maintain a **patient registry** with ability to report patient outcomes and other epidemiological information. Electronic information systems must be regarded as essential tools to the provision of quality services.

5. Have **auditing and quality control** mechanisms.

6. Have a **CME programme** to all HCPs involved in the management of the disorders.

7. Serve **a sufficient number of patients** to maintain staff experience.

8. Provide **patients with sufficient knowledge** and information to promote **partnership models** and self-management support.

9. Have a contribution to **research** as evidenced by peer reviewed publications.

10. **Networking** with secondary centres but also with other centres of expertise nationally and internationally.

11. Maintain close **links with patient organisations** and other community resources.

In addition, there must be evidence **of health system support** and **free access** of patients to treatment modalities. The centres' administrative structure, working hours and clinical space availability must also be taken into consideration, with the **patient experience** in mind. Any deficiencies and gaps must be identified and corrected.

There is also a need to assess the **experience of professional staff**.

Patient perceptions of the quality of the services, should be monitored and taken into account in quality assessment. A separate questionnaire is designed, to assess patient views of the services and their relationship with the staff. Such a system will increase patient confidence in the services and may have a positive effect on patient compliance.

PHASE A

The Centre should meet the following requirements:

- The centre clearly serves benign hematology patients and is best, if possible, not to include malignancies as they constitute a dangerous and vulnerable cohabitator.
- Adequate number of patients of each diagnostic group: at least 50 thalassaemia patients and/or 50 SCD patients for the center to be regarded as experienced.
- Continuity of care which is safeguarded by low staff turnover and the presence of experienced and qualified caregivers.
- Clinical records with lifetime data are kept.
- Multidisciplinary care with a referral system where necessary, and collaboration with in-patient services.
- The centre should be associated with a clinical transfusion centre(s), blood bank(s), laboratory(ies), and other image centre(s) the quality of which is known, otherwise the whole patient journey of diagnosis, prevention, and management falls apart.
- Networking with secondary centres as well as with other centres of excellence, nationally or internationally, is an added value. A twinning program with an academic centre is also an additional advantage.
- Any existing electronic health record must fulfil all the requirements of patient safety including patient consent, confidentiality and anonymization in data storage and sharing of data for research.
- Barriers to patient access, including distance, language, cultural or religious barriers are considered and dealt with.
- Respect for patient rights and time is a must in all cases.
- Informed consent for all procedures is obtained.

PHASE A: CHECKLIST

To be completed by the centre and returned to TIF

Centre identification:

Clinic /Department:……

Name of Hospital: ……..

Address……...

City…….. Country……..Zip code…..……

Tel……..…Email……...……

Staff

Administrative Director……....…

Clinical Director (if different) ……

Is there an organisation chart of key personnel? Y/N

Medical Specialities:

Specialty	Yes / No	Number
Haematologist		
Paediatrician		
Internist		

Are you connected on a regular basis with doctors from other specialisations or do your patients go to specialists of their choice?

Complete the table below if you are connected on regular basis with doctors from other specializations:

Specialty	Yes/No	Number
Endocrinologist		
Cardiologist		
Gynaecologist		
Hepatologist		
Psychologist		

Nursing staff
Head nurse:

Years in centre……

2nd head nurse or assistant……..……

Years in centre……..……

Total number of nurses……..……

Social worker: Is there a dedicate worker? Y/N

Doctor/ patient ratio …..
Nurse/ patient ratio……

Support for **continuous medical education** (CME) for all levels of staff:

Activity	No provision	Provision occasionally	Provision for regular support
Support to attend international conferences			
Fellowships for staff			
Webinars facilitated			
Teaching facilities within centre			
Centre teaches staff from other centres, GP's, Nurses etc.			

Administrative Budget:
Attached to hospital: Y/N

a) Ministry Hospital ☐
b) University ☐
c) Private ☐

Separate unit from Hospital Y/N

The centres serve:

- Paediatric patients exclusively Y/N
- Adult patients (over the age of 16y) Y/N
- Mixed age unit Y/N

Budget
Budget from: (more than one answer possible)

a) Ministry ☐
b) Ministry but independent budget from the hospital ☐
c) Donations ☐
d) NGO supported entirely ☐
e) Private (out of pocket and/or insurance finance) ☐

- Is the funding sustainable? Comment……..…..
- Is there political commitment to support the centre long term? Comment……..

Patient support:

a) Full financial coverage for all patients ☐
b) Full financial coverage according to age (e.g. children only) ☐
c) Coverage according to family income ☐
d) Partial coverage ☐

If partial coverage:

a) Out-of-pocket expenses for blood transfusion ☐
b) Out-of-pocket expenses for consumables ☐
c) Out-of-pocket expenses for iron chelation ☐
d) Out-of-pocket expenses for laboratory tests ☐
e) Out-of-pocket expenses for MRI ☐

Centre Accreditation:

Has the centre gained accreditation from any international body:

JACIE Y/N **JCI** Y/N **ISO** Y/N **AABB** Y/N

Functions:

- Is the centre a day care centre? Y/N
- What are the daily working hours of the centre? from…..am to …..pm
- Connectivity with inpatient services…….... (describe)

- Connectivity with emergency departments ……...…..…(describe)

- Connectivity to a patient support association…….……..(describe)

Centre involved in **research**:

1. Peer reviewed publications Y/N (provide list)
2. Research grants Y/N (provide list)
3. Clinical trial involvement Y/N (provide list)
4. Basic research ☐

Centre involved in **teaching**:

1. Medical undergraduates ☐
2. Medical postgraduates ☐
3. Nurses ☐
4. Laboratory staff ☐

Epidemiological information

Does the centre maintain a **patient registry**: Y/N?
If yes:

a) Is it paper based Y/N…. Electronic Y/N….
b) Is it confined to the patients followed in the centre Y/N

c) Is it part of a hospital general registry Y/N
d) Is it part of a regional registry Y/N
e) Is it part of the national haemoglobinopathy register Y/N
f) Is it part of a rare disease register Y/N
g) Are legal and ethical regulations followed in sharing patient data (e.g. informed patient consent)? Y/N

How many **patients** are currently being followed in the centre:
a) Transfusion dependent beta thalassaemia (TDT) ……
b) Non-transfusion dependent beta thalassaemia (NTDT)……
c) HbE/beta thalassaemia……..
d) HbH disease……
e) SCD patients (S/S,S/C or S/beta thalassaemia)…..
f) Other anaemias (please list)

Please provide an **age distribution** of the TDT patients (present a graph please)
a) Number of patients 1-10 years……
b) Number of patients 11-20 years…..
c) Number of patients 21- 30 years……
d) Number of patients 31-40 years……
e) Number of patients 41-50 years…….
f) Number of patients over 50 years……

Patient **deaths**/year:
- Current year….
- Previous year….
- Last 5 years….

Patient **education**: How many of the TDT patients are in the following educational groups:
a) Primary education (completed or not) no education…..
b) Vocational secondary education…..
c) Full secondary education…
d) Higher vocational, bachelors degree….
e) University mastersdegree and higher…..

What is the carrier rate, in your region/country?:
a) Beta thalassaemia genes ….. (from a population of……)
b) HbE genes …… (from a population of…..)
c) HbS genes …… (from a population of…..)

What is the expected birth incidence for thalassaemia in your region/country?.....

Basic Equipment

Availability of essential supplies
i. All three iron chelating agents available ☐
ii. No interruptions in supplies of drugs ☐
iii. No delays in blood transfusions due to inadequate supplies ☐
iv. Blood filtration available for all transfusion units ☐
v. Infusion pumps in adequate supply ☐

THE TIF RENZO GALANELLO FELLOWSHIP PROGRAMME

Introduction

TIF, in the context of its educational programme, offers each year the Renzo Galanello Fellowship Programme. This fellowship was launched in 2013 in honour of the late Professor Renzo Galanello, a pioneer in the field of thalassaemia research and management. It is offered to physicians, specialists in the field of haematology, paediatrics or internal medicine who are active in the field of heamoglobin disorders. Currently this fellowship is offered through the Join Red Cell Unit, Haematology Department at the University College London, NHS Foundation Trust in London, UK under the leadership of Dr Perla Eleftheriou consultant Haematologist.

Sadly, still in many countries there is a lack of trained medical staff and as result, healthcare of haemoglobinopathy patients is less than optimum. In an effort to widely spread this fellowship, TIF aims to collaborate with other reference centres as well. Following the validation of the centre as a TIF Reference Centre that meet all the requirements, then TIF could offer this fellowship programme.

Target Audience & Aim of the training.

This programme is addressed exclusively to medically educated health care professionals who are active in the field of heamoglobin disorders – thalassaemia and/or Sickle Cell Disease (SCD) and it aims to provide a more advanced training to already knowledgeable physicians that treat patients with these disorders. Through this training the fellows will receive a more comprehensive, expert knowledge on how to address the prevention and management of these disorders in their countries and provide meaningful and scientifically based recommendations to their governments and policy makers for improving programmes and policies for addressing them more effectively.

It is a widely known fact that if these disorders left unaddressed or sub-optimally addressed, they lead to significantly high rate of morbidity and premature death of the patients, pain and disabilities while at the same time huge medical, public health, social and economic repercussions to the Governments. Addressing them appropriately with expert knowledge and quality practices, these genetic, hereditary, chronic disease is a key factor to the sustainability and resilience of the public health care and social systems in country.

Candidates & Selection Committee

The candidates and their employers must be committed to working in the field of haemoglobinopathies at their current institution of employment for a period of at least 3 years after the fellowship so that the candidate also trains other medical specialists in the field during this period.

- A letter of consent for this must be sent along with each candidate's application, both by the candidate himself/herself and by the employer. The employer can be the director of the institution where the candidate is employed or an assigned by the Ministry of Health of the candidate's country official.
- Candidates should not work in a private hospital where patients will need to pay for his/her services.
- Priority will be given to candidates who have specialist training in Haemoatology or Paediatrics or Internal Medicine and at least 2 years of experience in working with patients with Thalassaemia or Sickle Cell Disease in a government hospital.
- In cases where the selection committee feels that specialised training in one or more specific aspects of the treatment or monitoring of haemoglobin disorders is essential to be promoted in a specific country or for this specific candidate, their training could be tailored and offered for a smaller duration on the particular specialised topic. Such could be training on endocrine or hepatic or cardiac monitoring of haemoglobinopathy patients.
- The candidates must provide information on the number of patients and types of haemoglobinopathy attending in his/her clinic and the type and quality of the provided services.
- The applicants should understand and speak English fluently or speak the local language. If communication will be carried out in English, applicants who are not native English speakers need to provide proof of their proficiency in this language.
- No more than one application per host institution will be considered at one time.

- Final approval will be obtained through common consultation and consensus between the training centre and TIF. Hence, the application of each candidate will be reviewed by the selection committee that will be comprised of:
    - 2 members of TIF's Scientific Advisory Board on behalf of TIF
    - 2 chief medical specialists on behalf of the training centre.

TIF RENZO GALANELLO FELLOWSHIP: CURRENT PROGRAMME

- **Reference Centre & Faculty**

The Renzo Galanello Fellowship Programme is currently offered through the Join Red Cell Unit,
Haematology Department at the University College London, NHS Foundation Trust in London, UK, which is headed by Professor John Porter, Professor of Haematology, under the leadership and coordination of Dr Perla Eleftheriou Consultant Haematologist with a contribution of a multidisciplinary team which is composed by distinguished medical specialists of the department and of across different relevant medical and scientific disciplines including haematology consultants, consultant cardiologists, consultant endocrinologists, clinical psychologists and red cell specialist nurses.

- **Duration**

The duration of the programme varies between 1– 4 weeks depending on the needs of the applicant(s) and/or its format - virtual/condensed training or with physical attendance.

- **Training Programme**

Consultant Haematologist, Dr Perla Eleftheriou, Lead of Red Cell Haematology Department of UCLH, has constructed a very comprehensive programme with interactive lectures on significant topics. Presentations held by the lecturers are oftentimes customised to address the specific needs of the fellows and their respective countries.
Dr Eleftheriou also coordinates the administration aspect of this programme including the relevant paperwork and actions for facilitating and authorising the fellows' entry in the college hospital, to accompany Dr Eleftheriou in her ward rounds, to be present in patient cases discussions, to use the library etc.

- **Official Reports**

Please visit https://thalassaemia.org.cy/what-we-do/education/fellowships-preceptorships/renzo-galanello/ to view the Official Reports of the TIF Renzo Galanello Fellowship Programme as from 2018. You may view all the details on the 2023 fellowship, including the official report and training programme here.

- **Funding**

TIF is covering the cost of the successful candidates' airfare to and from their country, their accommodation and it provides a stipend for their daily transportation and basic living expenses. The Federation does not have any further financial obligation.

- **Following the Training**

Following the completion of the Renzo Galanello Fellowship Training Programme, the candidates automatically become members of TIF's International Health Professionals Network and TIF Associate members. Through this role, they initiate a close collaboration with TIF towards strengthening the efforts in their countries to improve the policies related to better health and quality of lives of patients with haemoglobin disorders.

ABOUT THALASSAEMIA INTERANTIONAL FEDERATION (TIF)

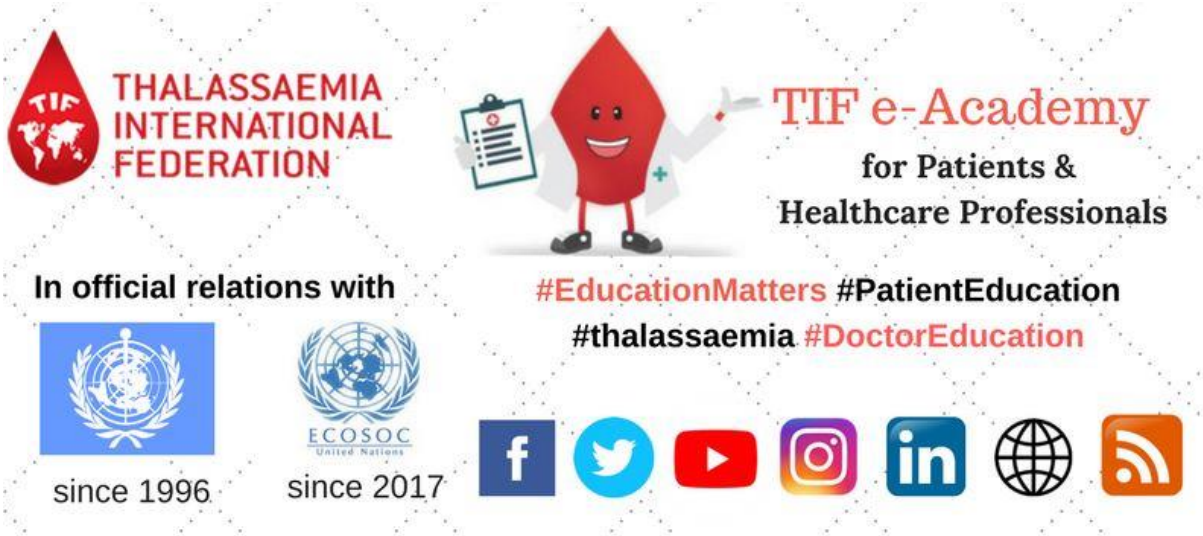
TIF

The Thalassaemia International Federation (TIF) was founded by patients with thalassaemia and their parents in 1986 and registered in Cyprus as a Non-Profit, Non- Governmental Organisation, under the Cyprus Company Law in 1987.
Governed by its constitution, the Federation is presided over by an 18-member Board of Directors (maximum two representatives per country), elected for a four-year term and comprised of 50% of patients with thalassaemia.

MISSION and VISION

MISSION: The development and implementation of national disease-specific programmes for thalassaemia in every country, which encompass both the component of prevention and that of management.

VISION: Establishment of equal access to quality health, social and other care for all patients with thalassaemia globally, in a truly patient-centred health care setting. Noteworthy and although TIF has been established to address, and by constitution to serve the needs of patients with thalassaemia globally through its activities, sickle cell disease and many other issues pertaining to public health are also addressed in the context of TIF's activities to a significant extent.



ANNEX I

a) What is Quality Care

Even though health care professionals and services in general are motivated to achieve the highest outcomes in the care of patients, such services, however, are not always supported to provide optimum care, which is patient centred and safe, resulting in the desired outcomes. This is particularly so when chronic and rare diseases are concerned which indeed constitutes diseases with a significant burden on health services and they require most often complex and multidisciplinary care models.

Health care quality is the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes. Quality of care plays an important role in the triad describing the intricate relationships between quality, cost, and accessibility of health care within a community and a national healthcare system. Researchers measure health care quality to identify problems caused by overuse, underuse, or misuse of health resources. In 1999, the Institute of Medicine (IOM) released six domains to measure and describe quality of care in health. Based on IOM, quality in health care should be:

1. ***Safe*** - avoiding injuries to patients from care that is intended to help them.
2. ***Effective*** - avoiding overuse and misuse of care.
3. ***Patient-Centred*** - providing care that is unique to patients' needs.
4. ***Timely*** - reducing wait times and harmful delays for patients and providers.
5. ***Efficient*** - avoiding waste of equipment, supplies, ideas and energy.
6. ***Equitable*** - providing care that does not vary across intrinsic personal characteristics.

According to a WHO document, "there is evidence that internal mechanisms of organisational and personal development have repeatedly failed to ensure safety, efficiency, best practice and public accountability". It was therefore suggested that mechanisms of external regulation may contribute to quality improvement.

b) Multidisciplinary Care

Since thalassaemia and Sickle Cell Disease are poly-organic in nature, have lifelong dependency on blood and are genetic in aetiology, must bear considerable medical attention from various medical specialisations including medical transfusionist, cardiologist, endocrinologist, hepatologist, nephrologist, psychologist, and paediatrician.

TIF Standards for Quality Haemoglobinopathy Care Centres Checklists Standards for consideration in assessing centres for Hb disorders. (based on JCI standards)

1. Governance

- The existence of a hierarchical structure, ordained by law and policy. This should include a chief executive/ managing director and a professional team which is coordinated and includes multidisciplinary services, recognising the complex pathology of haemoglobin disorders.
- A clear definition of the centre's mission and the existence of policies and programmes to fulfil the mission.
- Ensuring staff qualifications, experience, and continual education
- Monitoring and evaluating the functions of the centre by the management, including staff performance and patient safety.
- The existence of plans for quality improvement and advocacy to health authorities
- Connection with patient support associations, with patient representation on advisory bodies. Taking into account all stakeholders views regarding matters of priority and focus in any quality improvement activity.
- All decisions are based on data, obtained through patient records and outcomes, as well as any new developments that have been noted through publications and trials.
- A culture promoting ethical practices in all aspects of administration and clinical care. Considering internationally accepted patients' rights.

2. Safety concerns

- Staff education on safety is programmed.
- Patient identification is clear in individual records (electronic or paper based), blood transfusions and lab results.
- There is effective patient communication and explanation of all interventions.
- Hemovigilance and pharmacovigilance are practised, including drug safety alerts.

- There are evidence-based hand hygiene guidelines
- There are measures to reduce accidents, such as falls in the centre. A secure environment is planned and regularly inspected. Hazardous material handling and disposal (such as needles) is part of the centre's daily procedures.
- There are treatment rooms, and resuscitation equipment.
- Fire safety and certification by the country's fire services is available. This includes regular testing of any devices required for fire control.
- Cigarette and other smoking is forbidden on the premises
- Emergency procedures are in-place in the event of power and water cuts or contamination. Monitoring water quality is performed regularly.

3. Access to care

- The centre clearly serves benign haematology patients and does include malignancies as they constitute a dangerous and vulnerable cohabitator.
- Patient flow: there must be adequate numbers of patients of each diagnostic group: at least 50 thalassaemia patients and/or 50 SCD patients for the centre to be regarded as experienced.
- Continuity of care is safeguarded by low staff turnover and the presence of experienced and qualified caregivers.
- Clinical records with lifetime data are kept.
- Multidisciplinary care is provided with a referral system where necessary, and collaboration with in-patient services.
- Networking with secondary centres as well as with other centres of excellence, nationally or internationally is an added value. A twinning programme with an academic centre is also an additional advantage.
- Any existing electronic health record must fulfil all the requirements of patient safety, including patient consent, confidentiality and anonymization in data storage and sharing of data for research.
- Barriers to patient access, including distance, language, cultural or religious barriers are considered and dealt with
- Respect for patient rights and time is a must in all cases.
- Informed consent for all procedures is obtained.

4. Partnership model

- Adequate information to patients/families about the disease and any treatment decisions, including possible side effects, is always provided.
- Patients are given choices about their treatment.
- Self-management is encouraged.
- Special attention to patient adherence is given and the patients supported appropriately.
- Workshops for patients/families are held regularly, at least once a year.

5. Guidelines and standards for clinical care

- Evidence based national guidelines, put together by experts in the field or international guideline (e.g. TIF's) are used in the centre and adhered to.
- Pain screening is performed, and a pain management system is in place.
- Assessing the quality of laboratory and other technologies used to monitor patients is the responsibility of the clinical team which must alert the providers of any divergent or inaccurate results.
- Infection control procedures are part of the clinical standards of the centre.
- Availability of food during day care is necessary and the quality and nutritional value must be monitored.
- Blood transfusion procedures and standards according to international directives are kept.
- Any medical treatment, such As IV fluids, exchange transfusions etc are provided according to standards that ensure patient safety.
- Continual medical and other professional education are part of the centres long term programme.
- Staff qualifications, skills knowledge and experience are defined and described along with the job description of each.
- Staff/patient ratio is defined approximately as 1 doctor per 100 patients and 1 nurse per 50 patients.

6. Quality improvement

- Having surveyed all aspects of the service, and noted all strengths and weaknesses, the survey team will present a report and also suggestions for quality improvement where necessary.
- Quality improvement is a systematic approach to changes aiming to upgrade services and correct any deficiencies in the governance, structure and functions of the service. "Quality improvement includes better patient experience and outcomes, by changing provider behaviour" (Dr John Ovretveit: "Does improving quality save money?")
- The way in which change is introduced and implemented is a matter of concern and may require expert advice. In this process the following are considered:
- External influences, such as governmental policies or interest, budgetary support, professional requirements.
- Understanding the issues involved at all levels, including why a problem exists.

- Setting goals and monitoring progress
- Choosing the tools to bring about change. These could be skills development, computerisation, updating guidelines etc.
- Full staff engagement is necessary. There often needs to be a multidisciplinary approach to change making.
- The patient's voice must be involved in all stages of quality improvement. Patient/families can also effectively monitor the effects and benefits of change since they experience the whole "patient pathway".
- Studying other centres experience in change making: have the changes been successful elsewhere?

7. Information Management

- Patient records (paper or electronic) are kept with due consideration to confidentiality, security and accuracy of data.
- The retention time of records in a haemoglobinopathy setting, is lifelong, since the current clinical condition may be influenced by past events and disease control (such as iron levels)
- Standard diagnosis codes are kept (e.g. ICD10)
- E-health systems are assessed and tested prior to implementation, for quality and patient safety.
- Protection against loss, unauthorised access or use is ensured.
- Policies and procedures concerning record keeping are clearly directed to all the staff, through documents and training.
- The patient should be clearly identified on each record.
- Those authorised to have access to clinical records are clearly defined.

ANNEX II

PHASE B: CHECKLIST

To be completed prior to TIF's on-site visit and discussed during the visit

Centre identification:

Title……

Address……...

City…… Country……..Zip code…..……

Tel…… Email……..……

Staff

Administrative Director .....(Attach CV)

Clinical Director (if different)..... (Attach CV)

- Is there an organisation chart of key personnel? Y/N
- **Medical personnel**: (expand table according to numbers of doctors)

1. Roles

Role	Time for the Center (% of full time)	Specialty (Hematology, Pediatrics, Internal Med, others)	Name/s	Age/s	Years of service in the centre
Clinical Director					

2. Supporting medical (expand table according to numbers of specialists and attach their CVs)

Specialty	Name/s	Age/s	Years of service to the centre
Endocrinologist			
Cardiologist			
Fertility team			
Andrologist			
Hepatologist			
Psychologist			

NB: These specialists are not expected to be employed fulltime within the centre, rather employed in hospital departments, but committed to collaborate and serve thalassaemia patients having gained experience in the specific complications of the disease.

3. Nursing staff

Head nurse
Name……
Years in centre (Full-time / Part-time) ……

2nd head nurse or assistant
Name……..……
Years in centre (Full-time / Part-time) ……..……

Total number of nurses……..……

4. How efficient the social services are at the centre/hospital/territory level and how pro-active the centre is in activating them?

5. Support for **continuous medical education** (CME) for all levels of staff:

Activity	No provision	Provision occasionally	Provision for regular support
Support to attend international conferences			
Fellowships for staff			
Webinars facilitated			
Teaching facilities within centre			
Centre teaches staff from other centres, GP's, Nurses etc.			

6. The centre serves:
- Paediatric patients exclusively Y/N
- Adult patients (over the age of 16y) Y/N
- Mixed age unit Y/N

7. Patient support:
- **a)** Full financial coverage for all patients □
- **b)** Full financial coverage according to age (e.g. children only) □
- **c)** Coverage according to family income □
- **d)** Partial coverage □
- **e)** No coverage (family expected to fully finance medical expenses) □

If partial coverage:
- **a)** Out-of-pocket expenses for blood transfusion □
- **b)** Out-of-pocket expenses for consumables □
- **c)** Out-of-pocket expenses for iron chelation □
- **d)** Out-of-pocket expenses for laboratory tests □
- **e)** Out-of-pocket expenses for MRI □

8. Functions:

- Is the centre a day care centre? Y/N
- What are the daily working hours of the centre? from…..am to ..... pm

- Connectivity with inpatient services… ..... (describe)
- Connectivity with emergency departments..... (describe)
- Connectivity to a patient support association .....(describe)

9. Centre involved in **research**:

1. Peer reviewed publications Y/N (provide list)
2. Research grants Y/N (provide list)
3. Clinical trial involvement Y/N (provide list)
4. Research personnel Y/N. If Y, specify:
    - Data manager Y/N, **Time for the Center (% of full time)**……..
    - Research nurse Y/N, **Time for the Center (% of full time)**……..
    - Other Y/N, specify…… **Time for the Center (% of full time)**……..
5. Basic research

10. Centre involved in **teaching**:

1. Medical undergraduates
2. Medical postgraduates
3. Nurses
4. Laboratory staff

Teaching in English: Y/N, specify…….

11. Epidemiological information

Does the centre maintain a **patient registry**:
Y/N <u>If yes</u>:

a) Is it paper based Y/N…. Electronic Y/N….
b) Is it confined to the patients followed in the centre Y/N
c) Is it part of a hospital general registry Y/N

d) Is it part of a regional registry Y/N
e) Is it part of the national haemoglobinopathy register Y/N
f) Is it part of a rare disease register Y/N
g) Are legal and ethical regulations followed in sharing patient data (e.g. informed patient consent)? Y/N

12. How many **patients** are currently being followed in the centre:

a) Transfusion dependent beta thalassaemia (TDT) ……
b) Non-transfusion dependent beta thalassaemia (NTDT)……
c) HbE/beta thalassaemia……..

d) HbH disease……

e) SCD patients (S/S,S/C or S/beta thalassaemia)…..

f) Other anaemias (please list)

Please provide an **age distribution** of the TDT patients (present a graph please)

a) Number of patients 1-10 years……

b) Number of patients 11-20 years…..

c) Number of patients 21- 30 years……

d) Number of patients 31-40 years……

e) Number of patients 41-50 years…….

f) Number of patients over 50 years……

Please provide an **age distribution** of the NTDT patients

a) Number of patients 1-10 years……

b) Number of patients 11-20 years…..

c) Number of patients 21- 30 years……

d) Number of patients 31-40 years……

e) Number of patients 41-50 years…….

f) Number of patients over 50 years……

Please provide an **age distribution** of the SCD patients

g) Number of patients 1-10 years……

h) Number of patients 11-20 years…..

i) Number of patients 21- 30 years……

j) Number of patients 31-40 years……

k) Number of patients 41-50 years…….

l) Number of patients over 50 years……

13. What is the carrier rate, in your region/ country?

a) Beta thalassaemia genes ….. (from a population of……)

b) HbE genes …… (from a population of)

c) HbS genes …… (from a population of)

What is the observed birth incidence for thalassaemia in your region/country?

.

14. Diagnosis:

Expertise in phenotypic diagnosis of Hb disorders:

- Lab within centre Y/N
- Lab within hospital Y/N
- Based on other reference labs Y/N, specify……..

Expertise in molecular diagnosis of molecular disorders

- Lab within centre Y/N
- Lab within hospital Y/N
- Based on other reference labs Y/N, specify……..
- Neonatal screening programme for SCD currently available Y/N

Is there a structured population screening programme: Y/N

- Is it run by the centre Y/N
- Do you have a protocol or an algorithm for antenatal screening?

15. Diagnosis of long-term complications:

Which of the following, are practiced in the centre?

- Annual examination of patients by a cardiologist Y/N
  - Is the cardiologist experienced in thalassaemia heart disease? Y/N
  - Is cardiac MRI with T2* provided annually? Y/N
- Annual examination by an endocrinologist Y/N
  - Is the endocrinologist dedicated and experienced in endocrine complications ofthe disease? Y/N

16. Do patients have to pay for MRI examinations?

Is liver iron measured annually? Y/N
- Is it measured by T2* Y/N
- Ferriscan Y/N
- Does the clinic know if the software used is validated? Y/N

17. Do patients benefit from these examinations (annually or at individual basis according to age/risk)

a. Transcranial Doppler (if SCD children)? Y/N
b. Abdominal U/S? Y/N
c. DEXA measurements of BMD Y/N

18. Are patients seen by psychologist, at the centre? Y/N

a. Are they referred to the psychologist according to personal needs? Y/N
b. Does the specialist see all patients? Y/N
c. Is the service free of charge? Y/N

19. Do you conduct regular meetings with the key medical disciplines? Y/N
How often?

20. Evidence based guidelines

a) Not available
b) Available but not integrated in the care delivery
c) Available and used as standards of care in the daily management
If (c) is the answer how are the guidelines made available to all involved?

The guidelines used:

a) TIF guidelines Y/N
b) Nationally prepared standards Y/N
c) Local standards prepared at the centre Y/N

If (b) or (c) is the answer, please provide a copy and explain how they were developed.
Availability: Digitally ….., and/or In the library …..

21. Continual Medical Education CME

a) Provided sporadically in the centre ☐
b) Staff sponsored to attend conferences, within country and international ☐
c) Staff given fellowships to other centres of expertise ☐
d) Follow on-line courses on thalassaemia and SCD management ☐
Provide evidence of (b), (c), (d)

22. <u>Continuity of Care</u>

a) Medical staff is all permanent
b) Junior staff rotate while seniors are permanent
c) There are no permanent doctors in the centre since all rotate

AUDITING AND QUALITY CONTROL MECHANISMS

23. Adverse events:

a) Is the staff trained and do they comply with the hemovigilance system, reporting events in blood transfusion Y/N (review evidence of annual reports)

b) Is the medical staff compliant with the pharmacovigilance system? Y/N (review evidence reports in the past 3 years)

c) Is there an internal system of reporting and evaluating adverse events in centers? Y/N

d) Is there an internal system for investigating and responding to complaints? Y/N

24. Auditing:

- Compliance with centre procedures and standards Y/N
- Compliance with clinical guidelines: describe methods in use by the directors of the centre……..
- Producing an annual report Y/N
- Recording patient outcomes:
  - Average and range of pre-transfusion Hb Y/N
  - Are there longitudinal records kept and used (individual and population)?

25. Please provide a table with the Center's TDT, NTDT, SCD patients separately and where appropriately of their average pre-transfusion hemoglobin, LIC, and Ferritin the past 3 years (2022- 2024), if possible, 2 years (2023 & 2024) mandatory.

26. What percentage of the patients are infected with HCV or HBV or HBV and HCV or HIV?

27. What percentage of patient with new infections diagnosed in the last 5 years (2019 – 2024) of HCV, HBV, HIV?

28. Do you a record of the social integration parameters of the adult patients? Please complete if this information is available:

- % single _____
- % married _____
- % divorced _____
- % employed _____
- % semi-employed _____
- % not employed _____
- % retired _____

29. Please provide the current age distribution of your patients as per diagnosis. A table of key endocrine, liver and cardiac complications.

Patient annual **deaths between 2018 – 2024.**
Please provide the cause of death as stated on the death certificate.

- 2024: _____
- 2023: _____
- 2022: _____
- 2021: _____
- 2020: _____
- 2019: _____
- 2018: _____

(Each centre should choose the patient outcomes they intend to record, without neglecting the basic morbidity and mortality data)

Clinical monitoring:

How does your centre carry out regular monitoring based on international recommendations including:

Guideline	Available in the Centre
Haematological	**1.** CBC, indices □ **2.** HPLC □ **3.** Capillary electrophoresis □ **4.** Other electrophoresis □
Molecular	**1.** For all cases □ **2.** Selected cases □ **3.** Not done □
HLA typing -of the patient Y/N -of the family Y/N	**1.** All new cases □ **2.** Not done □
Voluntary blood donation	**1.** Below 50% □ **2.** 75% □ **3.** 100% □
Before the first transfusion: extended red cell antigen typing, at least for C,E, Kell	**1.** Only ABO, Rh □ **2.** Extended antigen typing for all patients □
Before each transfusion: ABO, Rh(D) compatible blood	Done for all patients Y/N
Cross match and screen for new antibodies before each transfusion	**1.** All cases □ **2.** Selected cases □
Leukodepleted blood	**1.** Blood bank □ **2.** Pre-storage □ **3.** No filtration □

Washed red cells	**1.** All cases **2.** If indicated
Pre-transfusion Hb 9-10.5g/dl	**1.** All cases **2.** Some fall below **3.** Local guideline 8g/dl
Pre-transfusion Hb higher than standard for patients with heart complications	Y/N
Keep post-transfusion Hb below 14-15g/dl	Y/N
Liver fibrosis assessment	**1.** Only biopsy **2.** Fibroscan **3.** Other non-invasive methods
Chelation therapy cannot be effective unless taken regularly	**1.** Adherence support by staff **2.** Support by psychologist **3.** Patient left to self-regulate
All three chelating agents registered	**1.** All three provided according to the needs of each patient **2.** DFO not available **3.** DFX not available **4.** DFX for selected cases **5.** DFP not available **6.** DFP for selected cases
Chelation therapy free of charge	**1.** Free from government **2.** Free from NGO **3.** Free from insurance **4.** Partial out of pocket **5.** Totally out of pocket

Combination of DFO + DFP or other may be used	**1.** Not used **2.** Selected cases **3.** Only for in-patients
▪ **DFO:** ▪ Audiometry annually ▪ Ophthalmology annually ▪ If fever stop therapy temporarily and establish organism (yersinia or klebsiella) ▪ Do not give prochorphenazine ▪ Stop if hypersensitivity ▪ Stop if pregnancy	Y/N Y/N Y/N Y/N Y/N Y/N
▪ **DFP:** ▪ Neutrophil count every 1- 2 weeks ▪ Stop if ANC <500 ▪ Patient to report if symptoms of infection and stop if fever ▪ Stop if joint pains ▪ Watch liver function ▪ Stop if pregnancy	Y/N Y/N Y/N Y/N Y/N Y/N
▪ **DFX:** ▪ Avoid if renal disorder and creatinine clearance <60ml/min ▪ Avoid if liver impairment ▪ Monthly creatinine trends ▪ Monitor proteinuria ▪ Monitor liver function monthly ▪ Stop if pregnancy	 Y/N Y/N Y/N Y/N Y/N Y/N
▪ Treatment of Chronic hepatitis	**1.** Specialist consultation **2.** No specialist available **3.** Antivirals too expensive
Splenectomy	**1.** All patients **2.** Selected because of irreversible hypersplenism **3.** Selected because of spleen size
Immunoprophylaxis Before splenectomy	**1.** Always done **2.** Not available
Antibiotics post-splenectomy	**1.** Always **2.** Specific cases **3.** Not prescribed
Prevention of OPSIs	**1.** Patient education Y/N **2.** Seek immediate medical attention Y/N **3.** Dear doctor letter Y/N

Discontinuation of iron chelation if fever	**1.** Y/N **2.** DFO only Y/N **3.** Any chelator Y/N
Endocrine Disorders:	
Growth	**1.** Charts not used **2.** Charts in all children's' folders **3.** In some children's' folders
Deformities recorded	**1.** Y/N **2.** Serial pictures Y/N **3.** Xrays Y/N
Tanner scale for sexual development used from 8	Y/N
Endocrine Deficiencies: **Bone Disease (Osteoporosis**)	
Annual BMD	**1.** DEXA not available **2.** DEXA annual or as indicated according to age and condition

Nutritional status assessed	**1.** Vitamin D levels measured □ **2.** Vitamin D never measured □ **3.** Zinc levels measured every 6 months □
Examined by endocrinologist	**1.** Annually from 8-10 years □ **2.** Individual pace according to age and condition from 8-10 years □ **3.** Never □
Hormone measurements	**1.** By clinic □ **2.** By endocrinologist only □ **3.** Never □
General Examinations:	
Chemistry panel (including blood urea, creatinine and LFTs)	**1.** Every 3 months□ **2.** Every 6 months□ **3.** Annually □ **4.** Individual pace according to age/risk □ **5.** Never □
Dental care	**1.** Annual dental checks for all patients □ **2.** Left to patients □
Psychological Support:	
Cognitive defects	Patients referred for neuropsychological tests Y/N
Approaches for psychosocial support	**1.** Changes in institutional practices □ **2.** Group sessions □ **3.** Family therapy □ **4.** Patient camps □
Additional Lifestyle:	
Physical activity	**1.** Encouraged for all ages □ **2.** Adults after ergometry and cardiac assessment □ **3.** Discouraged in all patients □ **4.** Not discussed □
Calcium & Vit D supplements provided	All Y/N Individual prescription according to age/blood levels/risk Y/N
Folic acid	All Y/N Individual prescription according to age/blood levels/risk Y/N
Zinc supplements	All Y/N Individual prescription according to age/blood levels/risk Y/N

Vitamin E rich diet recommended	Y/N (To all patients?)
Vitamin C rich diet recommended	Y/N (To all patients?)
Vitamin E supplements	All Y/N Individual prescription according to age/blood levels/risk Y/N
Vitamin C supplements	All Y/N Individual prescription according to age/blood levels/chelation/risk Y/N
Dietary iron restriction	Y/N to TDT Patients Y/N to NTDT Patients All Y/N Individual prescription according to specific risk Y/N
Recommendations on smoking, alcohol, drug abuse	Y/N

Other functions of the centre:

Medical records	
	1. Available as paper files □ **2.** Available as electronic medical records □ **3.** Excel files only
Security of records	**1.** Implemented according to national law □ **2.** Transferred using encryption □ **3.** Transferred only to centres which also comply with security standards □ **4.** Staff trained for data protection □
Storage	**1.** Patient records kept for lifetime □ **2.** Records kept for 15 years □ **3.** Records kept for 5 years □ **4.** Records kept only for the current visit □
Traceability of records and samples	Codification is done: **1.** For traceability □ **2.** Confidentiality □ **3.** Established procedure to transfer data or samples □
Ownership	**1.** Patient ownership □ **2.** Patient consent to create a record □ **3.** Patient consent to share a record □ **4.** Patient consent to use data for research □
Research	**1.** Full explanation given to patients concerning a research project in which patient data are used □ **2.** Full explanation concerning volunteering for clinical trials, including risks and benefits □ **3.** Patient written consent for involvement in any research □

Networks	
Multidisciplinary meetings	**1.** Y/N. If Y, • in-presence only • web meeting only • mixed **2.** Mean number of cases discussed… **3.** Is there a report? Y/N **4.** Is the report shared with the patient? Y/N
Networking with secondary centres	**1.** Y/N. If Y, **2.** Topic: diagnosis Y/N How many per year? **3.** Topic: clinical Y/N How many per year? **4.** Topic: research Y/N How many per year?
Networking with reference centres in the country	**1.** Y/N. If Y, **2.** Topic: diagnosis Y/N How many per year? **3.** Topic: clinical Y/N How many per year? **4.** Topic: research Y/N How many per year?
Networking with international centres	**1.** Y/N. If Y, **2.** Topic: diagnosis Y/N How many per year? **3.** Topic: clinical Y/N How many per year? **4.** Topic: research Y/N How many per year?

Laboratory attached to centre	**1.** For diagnosis only **2.** For prevention
	1. Screening with basic haematology (indices, microscopy, HPLC, CE) **2.** Molecular support **3.** Prenatal diagnosis **4.** PGD
Genetic counselling	**1.** By Qualified counsellors **2.** By clinic doctors **3.** By nurses **4.** By laboratory staff
HSCT	
	1. Available in the centre/department/hospital **2.** Available in the area **3.** Available in the country **4.** Patients referred abroad
	1. Supported by government funds **2.** Out-of–pocket totally **3.** Out-of-pocket partially **4.** Other support
Patient Reported Outcomes and Expectations	
Quality of Life measures	**1.** Assessed by validated questionnaire Regularly **2.** Assessed only as part of a research project **3.** Has never been done
Questionnaires for patients' opinion	**1.** Regular **2.** Occasional **3.** Never

Patients' involvement	**1.** In advisory committees **2.** In clinical decision making that concerns them **3.** Encouraged in self-management **4.** Poor level of education so not involved
Information/education for patients	**1.** Leaflets **2.** Seminars/workshops **3.** Encouraged to use electronic media (apps, website) **4.** None of the above
Clinic times	**1.** Clinics work mornings only **2.** Transfusions after working/education hours **3.** Weekend transfusions allowed
Patients are informed of their rights	**1.** On admission **2.** Through written material **3.** Not considered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