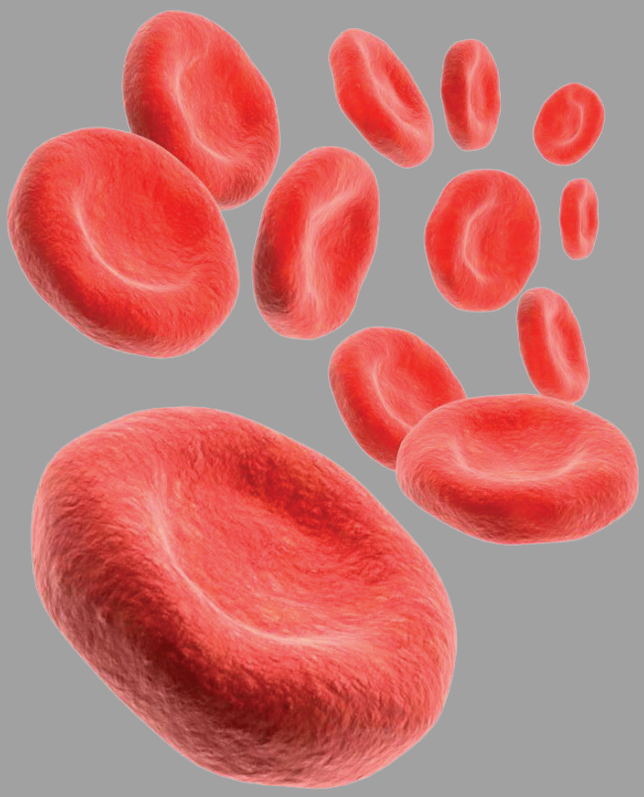
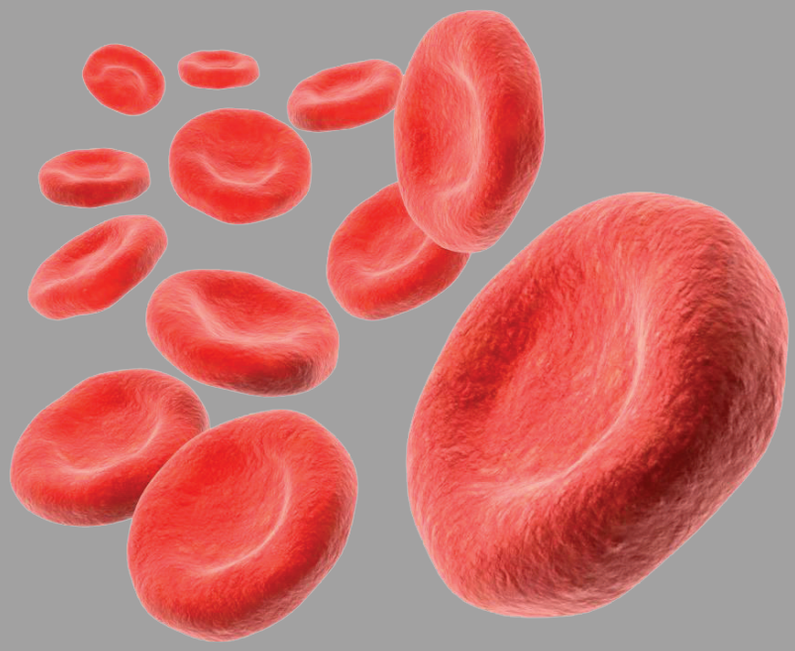


Therapeutic Phlebotomy

for patients with Hereditary Haemochromatosis

Model of Care



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Document Control

Document Info	Model of care for the delivery of therapeutic phlebotomy that is based on equity of access, carried out at the lowest level of complexity, in the most appropriate setting and nearest to people's homes. It defines the services currently available and recommend the best models for the delivery of phlebotomy.
Created By	Hereditary Haemochromatosis Working Group
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Approved By	The Acute Hospital Division, Health Service Executive The Primary Care Division, Health Service Executive Clinical Strategy and Programmes, Health Service Executive The Irish Society of Gastroenterology (ISG) The Irish Blood Transfusion Service (IBTS) Irish Haemochromatosis Association (IHA)
Responsible for Implementation	The Acute and Primary Care Division, Health Service Executive
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Revision Date	July 2019
Associated Documents:	• Hereditary Haemochromatosis – Diagnosis and Management from a GP perspective (1) • Model of Care for Therapeutic Phlebotomy

Disclaimer

Whilst every effort has been made by the authors and contributors of this document to ensure the information and material contained is complete, accurate and reflects international clinical best practice, errors or omissions may occur.

This guideline aids clinical judgement and does not replace it. In individual cases a healthcare professional may, after careful consideration, decide not to follow the guideline if it is deemed to be in the best interest of the patient.

This guideline should be read in conjunction with *Hereditary Haemochromatosis – Diagnosis and Management from a GP perspective* (1) and Model of Care for Hereditary Haemochromatosis.

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FOREWORD

Ireland has the highest reported prevalence of Hereditary Haemochromatosis (HH) in the world. It is essential that our healthcare system can respond to the needs of patients through the provision of appropriate and timely care. Over the years there have been many attempts to design a more equitable service for patients. In 2015, following a request from the Minister of Health, the HSE undertook to develop a model of care for Hereditary Haemochromatosis and for one of the most important aspects of treatment: Therapeutic Phlebotomy.

A working group was subsequently established to produce evidence-based guidelines on the diagnosis, screening, treatment and management of patients with HH. After listening to patient concerns, as articulated by the Irish Haemochromatosis Association, it was clear there was significant disparity in the way phlebotomy services are delivered in Ireland. To address this issue and ensure an equitable service for all, recommendations on the delivery and cost of treatment were developed. Our aim was to ensure that the management of patients could be delivered at the lowest level of complexity and in most appropriate setting. For the great majority of patients, this means care in the community, closest to their homes. This is in line with Future Health: A Strategic Framework for Reform which states that patients should be managed through primary care and be referred from primary care only when their needs are sufficiently complex. The MoC reflects these goals.

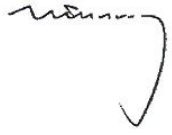
HH patients constitute a safe source of blood for transfusion and there is a need to align new recommendations with the needs of the Irish Blood Transfusion Service (IBTS). Recommendations have been made to ensure that, where possible, suitable blood is donated to the national blood supply.

These documents would not have been developed without the sponsorship and support of Joe Ryan, Acting Head of the Programme for Health Service Improvement and without the hard work of every member of the Working Group. The project began under the work of Aisling O'Sullivan, Project Manager and then brought to completion by Aisling Phelan, Project Manager. Both Aislings worked tirelessly with members of the working group and the IHA to ensure that we would complete the tasks set by the Minister and meet the expectations of patients. Thanks are also due to Dr. David Hanlon, Dr. Clifford Kiat, Dr. John Lee and Prof. Suzanne Norris who were the principal clinicians involved in the development of the model of care, and to Anna Capplis and Majella Jobling, nurses who run a phlebotomy clinic and who shared much valuable information with us. Thanks also to Noreen Curtin, CIT manager, Dr. Joe Clarke, GP and to Dr. William Murphy for representing the IBTS.

Finally, I would especially like to thank the dedication and hard work of Margaret Mullett, Chair of the Irish Haemochromatosis Association. She has advocated for better care for HH patients for many years with great energy and commitment and has been an articulate and passionate representative of the IHA in their engagements with the HSE and Department of Health.

This model of care outlines an accessible, equitable and quality service. Our collective ambition is now to work to implement these recommendations across all divisions in the HSE.

Sincerely,



Dr. Colm Henry, National Clinical Advisor and Group Lead Acute Hospitals

EVIDENCE BASED MEDICINE

Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.

In this document you will see levels of evidence using the GRADE system (2,3).

	Example	Note	
Quality of evidence			
High	Randomised trials that show consistent results, or observational studies with very large treatment effects.	Further research is very unlikely to change our confidence in the estimate of effect.	A
Moderate	Randomised trials with methodological limitations, or observational studies with large effect.	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.	B
Low and very Low	Observational studies without exceptional strengths, or randomized trials with very serious limitations; unsystematic clinical observations (e.g. case reports and case series; expert opinions) as evidence of very-low quality evidence.	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. Any estimate of effect is very uncertain.	C
Strength of recommendations*			
Strong	Defined as being 'confident that adherence to the recommendation will do more good than harm or that the net benefits are worth the costs'		1
Weak	Defined as being 'uncertain that adherence to the recommendation will do more good than harm OR that the net benefits are worth the costs'	The uncertainty associated with weak recommendations follows either from poor-quality evidence, or from closely balanced benefits versus downsides	2

* Factors that affect the strength of a recommendation are: (a) quality of evidence; (b) uncertainty about the balance between desirable and undesirable effect; (c) uncertainty or variability in values and preferences; (d) uncertainty about whether the intervention represents a wise use of resources.

ABBREVIATIONS

AASLD	American Association for the Study of Liver Diseases
EASL	European Association for the Study of the Liver
EFAPH	European Federation of Associations of Patients with Haemochromatosis
GP	General Practitioner
HCC	Hepatocellular Carcinoma
HFE-HH	*HFE*-associated hereditary hemochromatosis
HH	Hereditary Haemochromatosis (same as HFE-HH)
HSE	Health Service Executive
IBTS	Irish Blood Transfusion Service
SF	Serum Ferritin
TS	Transferrin Saturation

GLOSSARY OF TERMS

Care Model	An approved normative healthcare delivery framework
Clinical Governance	Clinical Governance is defined by the HSE as "Corporate Accountability for Clinical Performance" in the domains of quality, safety, access and cost.
Hereditary Haemochromatosis	It is a common inherited disorder in which excessive iron absorption may lead to increased body iron stores with deposition of iron in parenchymal cells of the liver, heart, pancreas and other organs.
HFE-gene	Hereditary haemochromatosis gene with cytogenetic location: 6p21.3
Secondary iron overload	Disorders, other than hereditary haemochromatosis, which give rise to iron overload are classified under the broad heading of secondary iron overload syndromes (usually iron-loading anaemias such as thalassemia major).
Phlebotomy	Incision of a vein for the removal or withdrawal of blood; also called venesection.

EXECUTIVE SUMMARY

- Hereditary Haemochromatosis (HH) is a common autosomal recessive disease resulting in excessive absorption of dietary iron from the intestine. Over time, excess iron accumulates in the parenchymal cells of organs including the liver, pancreas, heart and anterior pituitary causing damage.
- The treatment of HH consists of life-long phlebotomy therapy and monitoring of iron indices, in particular serum ferritin. The advocated standard practice is to maintain serum ferritin at 50–100 µg/L.
- Blood taken from patients with HH at phlebotomy should be made available for national blood transfusion services for the public good, if there is no medical contraindication and the patient has given consent.

Key Recommendations

I. Support the expansion of the IBTS and recommend that patients with hereditary haemochromatosis are referred onto the IBTS (where the facility is available, patient consent has been gained and referral criteria is met). This would ensure an increase in the national blood supply.

II. The IBTS should explore opportunities to coordinate with primary care to facilitate the donation of blood in the community e.g. setting up mobile clinics within GP clinics/CIT clinics.

III. The IBTS should consider the use of Double Red Cell Apheresis as it achieves iron depletion in HH patients in a shorter treatment period than therapeutic phlebotomy.

IV. GP's should be supported and encouraged to provide phlebotomy services for patients with Hereditary Haemochromatosis.

V. The ICGP should develop a list of GP's who provide therapeutic phlebotomy. This should be made available online.

VI. Support the expansion of the GP Minor Surgery Network Pilot which provides therapeutic phlebotomy for HH patients (expansion to 60 locations in 2016). This network will be geographically diverse to ensure patients can have local access to such services.

VII. The standards being developed by the GP Minor Surgery Network (with regard to sterility, disposal of waste and credentialing process) should be extended for use by any GP practice who would like to undertake therapeutic phlebotomy for their patients.

VIII. Where feasible and where the IBTS service is not currently available in the area, GP's should coordinate with the IBTS to set up a mobile clinic to allow the donation of blood to the national blood supply.

IX. Move hospital-based nurse-led phlebotomy clinics to the community e.g. service can be provided by Community Intervention Teams. The referring GP/Consultant is responsible for the overall clinical management of the patient.

X. Where feasible and where the IBTS service is not currently available in the area, CIT's should coordinate with the IBTS to set up a mobile clinic to allow the donation of blood to the national blood supply

XI. Patients should not be managed or receive therapeutic phlebotomy in an acute care setting unless they fulfil the criteria for hospital referral and intervention.

XII. Future care and phlebotomy requirements for patients who have been attending hospitals for their phlebotomy, could be transferred to the community if patients are deemed fit and fulfil the criteria for community level care.

XIII. In order to effect the transfer of patients from the acute to primary care setting it is essential that the cost incurred by the patient is addressed at policy level.

XIV. Dispose of blood bags (with set attached and needle guard activated) by alternative technology. Suitable packaging options include either a 30/60 litre yellow rigid bin with yellow lid (with absorbent material) or a placenta bin with a red lid. Check your local waste collection contractor to clarify the appropriate bin.

1. INTRODUCTION

1.1. BACKGROUND

Hereditary Haemochromatosis (HH) is a common autosomal recessive disease resulting in excessive absorption of dietary iron from the intestine. Over time, excess iron accumulates in the parenchymal cells of organs including the liver, pancreas, heart and anterior pituitary. The accumulated iron eventually leads to the impaired function of these organs, and in its most extreme form, the disease may manifest with potentially life-threatening complications. Early diagnosis and treatment prevent progressive disease, however if left untreated the condition can be fatal with the most common causes of death being decompensated cirrhosis, hepatocellular carcinoma (HCC), diabetes mellitus, and cardiomyopathy (4).

Ireland has the highest levels of this condition in the world (5), with research showing that approximately 1 in 83 people are predisposed to develop hereditary haemochromatosis (5,6).

The treatment for the management of HH is phlebotomy (venesection). Initially the treatment, aimed at reducing the iron in the body tissue to a normal range, may require weekly phlebotomies to reduce ferritin or iron store levels. Once normal levels have been achieved, maintenance may only require 2-4 phlebotomies per year. However, the frequency of maintenance phlebotomy varies among individuals, due to variable rates of iron re-accumulation (7). In Ireland, the majority of phlebotomies are currently undertaken in acute hospitals.

1.2. OBJECTIVE

The aim was to produce an integrated model of care for phlebotomy which addresses the following principles: proximity to patient's home, location of lowest complexity, equity of access, cost effectiveness and standardisation of policies.

It was developed based on the document *Future Health: A Strategic Framework for Reform of the Health Service (2012)* which states that patients will be **managed through primary care** and be referred from primary care only when their needs for care are sufficiently complex. The recommendations in the document reflect this objective.

This MoC is in line with the 5 Goals of the Health Service Executive Corporate Plan 2015-2017 (8), which are:

1. Promote health and wellbeing as part of everything we do so that people will be healthier;
2. Provide fair, equitable and timely access to quality, safe health services that people need;
3. Foster a culture that is honest, compassionate, transparent and accountable;
4. Engage, develop and value our workforce to deliver the best possible care and services to the people who depend on them;
5. Manage resources in a way that delivers best health outcomes, improves people's experience of using the service and demonstrates value for money.

This document relates to the treatment via phlebotomy of HFE-related haemochromatosis only. The treatment and service for patients with elevated serum ferritin that is due to secondary iron overload conditions, alcohol consumption, metabolic syndrome, obesity, chronic liver disease malignancy, infection or inflammation are not covered in this document.

1.3. WHY THIS MODEL OF CARE IS NEEDED

Recommendations to develop an equitable service for patients with HH were published in "*Report of Working Group set up by the Tánaiste in March, 2006 to examine the nature and extent of Haemochromatosis in Ireland and to advise her on the action necessary to address the problems caused by Haemochromatosis*" (9). Efforts to develop a model of care to address these issues have been ongoing with little progress. In 2015, following a request from the Minister of Health, this project was transferred under the joint governance of the HSE Acute Hospital Division (AHD) and the HSE Primary Care Division (PCD). In the absence of a programme of individual clinical lead, the National Clinical Advisor and Group Lead for Acute Hospitals was asked to assume the role for designated lead.

There is currently no model of care for therapeutic phlebotomy for people with HH in Ireland and there is considerable variation in the delivery, access and cost of phlebotomy services. Thus, there was a need to identify enabling measures to facilitate the provision of an equitable service for patients nationally. Phlebotomy services are currently delivered at a higher level of complexity than required, with the majority of patients managed in the acute setting. Consensus opinion believes that phlebotomy should not be done in a hospital unless absolutely necessary due to the expense, unnecessary use of resources, adverse impacts on patient experience and the distances travelled by patients to attend hospital clinics. The health system, through the Irish Blood Transfusion Service (IBTS) also has a legitimate need and social responsibility to maximise the supply and safety of blood donation, a central tenet

of which is that donations are made freely and altruistically. The aim is to treat patients in the community by aligning with existing primary care initiatives mainly the Irish Blood Transfusion Service (IBTS) and other services such as Community Intervention Teams (CITs) and the GP Minor Surgery Research Network Project.

This model of care was developed in tandem with a Model of Care for patients with Hereditary Haemochromatosis.

1.4. FEEDBACK FROM PATIENTS WITH HEREDITARY HAEMOCHROMATOSIS

A questionnaire sent to 250 patients with hereditary haemochromatosis in 2008 found that 75% of patients receive treatment at a hospital clinic and the majority of the remainder attend their GP. The average return distance from a patient's home to receive treatment is 30km and 90% of patients would be prepared to travel to a specialist donor/transfusion clinic even if it involved extra distance or time. Patients also reported that access to specific healthcare workers e.g. nurses/doctors is the most important criteria in choosing a donation site. See Appendix 2 for the report.

In May 2015, members of the Irish Haemochromatosis Association (IHA) agreed to carry out a survey of HH patients to determine from a patients perspective a) what problems are currently experienced regarding access to phlebotomy and b) what factors might be considered regarding improvement of access to phlebotomy. The results were submitted in June 2015. A summary of patient's concerns is as follows:

- length of time it takes to access first phlebotomy;
- access to phlebotomy only during working hours – inconvenient;
- difficulties for people in non-urban areas to access services – equity of access not equal;
- people in non-urban areas unable to donate blood to IBTS;
- some patients have had problems getting prescription from their GP for the IBTS;
- no list of GP surgeries providing phlebotomy available.

Cost

Patients report there is considerable variation in the cost of phlebotomy depending on whether a person attends a hospital or GP. Those who qualify for medical card do receive phlebotomy treatment free of charge, but have to attend hospital for treatment as phlebotomy is not covered by the GMS (General Medical Service Scheme) if carried out in a GP surgery. Due to this some elderly and vulnerable patients need to take sparse public transport/taxi to a hospital.

Patient's report some hospitals are not charging for their service and others hospitals are charging public patients the government levy of €75. Patients with private health care insurance are sometimes charged a day case rate.

Patients also report disparity in the access and cost of genetic testing. Genetic tests are being sent to public hospitals, private hospitals and private labs and sometimes the cost of lab analysis is being placed on the patient.

Access and Geography

There is disparity in the access to care across the country and there are reports of long waiting lists for treatment.

2. DELIVERY OF PHLEBOTOMY – CURRENT SITUATION

2.1. SURVEY OF SERVICES

Patients currently undergo therapeutic phlebotomy in a variety of settings including:

- Acute Clinics;
- Irish Blood Transfusion Service;
- General Practitioners;
- GP Minor Surgery Network (currently pilot scheme).

See Table 1 for the locations of phlebotomy services nationally. Please note this list was developed from feedback and thus may not be fully complete.

Table 1. Current Resources

Acute Clinics
Dublin North East Hospital Group • Beaumont Hospitals • St. Joseph's, Raheny • Louth County Hospital (*Day Haemochromatosis and Phlebotomy Services for Our Lady of Lourdes Hospital and Louth County Hospital are based in the Day Services Unit at Louth County Hospital*) • Connolly Hospital • Cavan General Hospital • Monaghan Hospital
Dublin East Hospital Group • St Vincent's University Hospital • Mater Misericordiae University Hospital • Midland Regional Hospital Mullingar • St Luke's Kilkenny • Our Lady's Hospital Navan • Wexford General Hospital • St Michael's Hospital
Dublin Midlands Hospital Group • St James' Hospital • Adelaide and Meath Hospital, Tallaght • Midland Regional Hospital, Portlaoise • Midland Regional Hospital, Tullamore • Naas General Hospital
West/North West Hospital Group • University Hospital Galway • Mayo General Hospital

• Sligo General Hospital • Roscommon General Hospital • Portiuncula General Hospital • Letterkenny General Hospital
South/South West Hospital Group • University Hospital Cork • Mercy University Hospital • University Hospital Waterford • University Hospital Kerry • Mallow General Hospital • Bantry General Hospital • South Tipperary General Hospital • South Infirmary Victoria University Hospital
University of Limerick Hospitals Group • St. John's Hospital Limerick • Ennis General Hospital • Nenagh General Hospital • University Hospital Limerick
IBTS Haemochromatosis Clinic Service
• Stillorgan, Dublin • D'Olier Street, Dublin • St Finbarrs Hospital, Cork • New service to open in Limerick in 2016
GP Minor Surgery Network
Pilot project: 24 GPs in 20 practices. Project aim is to expand to 60 practices by end of 2016. List of named GP Minor Surgery will be available in late 2016.
GP Practices
There are GP's providing phlebotomy services, however a list of GP's was unavailable

2.2. ACUTE CLINICS

In January 2016, a survey to Hospital Groups highlighted that the majority of patients are being treated in the acute setting. Hospital based services are typically provided within a day ward setting, with a smaller number run in outpatient clinics. Haemochromatosis services were reported to be run through:

- endoscopy unit;
- diabetic day centre;
- IV therapy suite;
- gastroenterology and hepatology clinic;
- haematology day ward.

Most patients are referred by their GP or from another hospital service, for both diagnostic work-up and therapeutic management.

Most services are a consultant led, nurse delivered, ambulatory services. In general, staff nurses are accountable and responsible for the day to day management and operation of the phlebotomy service with support and guidance of Consultant Gastroenterologist(s)/Hepatologist. Typically, a medical SHO provides advice as required on a day to day basis. The following is undertaken in a well-established nurse-led clinic:

- referral received from GP/Consultant, with diagnosis and treatment plan outlined;
- phone pre-assessment with patient carried out, appointment booked and if possible, information booklet sent to patient;
- treatment plan is implemented as per their Standard Operating Procedure;
- data on all patients inputted on a dedicated phlebotomy database and a patient's phlebotomy booklet completed;
- liaise with GP/consultant to co-ordinate patient investigations/changes to treatment plan;
- education available to patients and family to discuss impact of diagnosis and information on genetic screening of first degree relatives;
- actively involved in assessing quality of life issues e.g. health promotion education, alcohol intake, smoking cessation and addressing issues of raised BMI.

Advantages and Disadvantages

- Advantages: Established clinics that provide both therapeutic phlebotomy and clinical management of the patient.
- Disadvantages: Phlebotomy carried out at higher level of complexity than required. Uses clinic space for other services that could be undertaken in the hospital. Blood not donated to the IBTS.

2.3. GENERAL PRACTITIONER

General Practice

Some GP practices provide phlebotomy services. The ICGP document Hereditary Haemochromatosis: Diagnosis & Management from a GP Perspective (1) supports phlebotomy in GP practices. It states '*HH is particularly amenable to diagnosis, treatment and ongoing follow-up in the Primary Care setting. Treatment is by phlebotomy, which is*

feasible, if time consuming, in General Practice. Unfortunately phlebotomy is not covered under the GMS contract.'

Advantages and Disadvantages

- Advantages: Patients managed in the community out of the acute setting. Close to the patient's home. GP is in charge of both the clinical management and treatment of a patient.
- Disadvantages: Blood cannot be donated to the IBTS. Phlebotomy not covered under the GMS contract.

GP Minor Surgery Network

The GP Minor Surgery Network pilot project was commenced on 1st August 2015 with 24 GP Surgeons in 20 practices across eleven counties performing and recording a wide range of surgical procedures. Therapeutic phlebotomy for haemochromatosis is included in the list of surgical procedures that is provided by this network. A full analysis of the numbers of phlebotomies undertaken and whether they are GMS or Non GMS will be available in July 2016 when the analysis is complete.

Part of the pilot is to agree standards with regard to sterility, disposal of waste and develop a credentialing process for GPs and practice locations. It is hoped that a national network of GPs and locations will be developed with the planned expansion of the pilot. These locations will be geographically diverse to ensure patients can have local access to such services.

Advantages and Disadvantages

- Advantages: As for GP but GP Minor Surgery network will have a set of agreed standards for quality and safety and have a credentialing process.
- Disadvantages: As for GP but the pilot project may not be continued.

2.4. THE IRISH BLOOD TRANSFUSION SERVICE

The IBTS currently provide phlebotomy for HH patients with stable ferritin who meet the referral criteria whether they are eligible or non-eligible for blood donation. The referral criteria is documented in https://www.giveblood.ie/Clinical_Services/Haemochromatosis/BT0587.pdf. Phlebotomy can be undertaken up to 4 times per year with a minimum of 90 days between each phlebotomy. Currently the patients are registered on a special panel, and undergo a standard IBTS phlebotomy. Non-donor's blood is collected into special "dry" packs (no anti-coagulant) and is never used for transfusion.

By March 2016, approximately 1,417 patients have attended the IBTS for treatment by the service provided in Dublin (Stillorgan Centre and D'Olier Street) and St Finbarrs Hospital, Cork.

The IBTS is currently providing a service as follows:

- In Stillorgan, the IBTS operates a full care model where the IBTS manages the ongoing care of the Haemochromatosis patient, while performing the necessary phlebotomy as required. The patient must attend their referring clinician for annual review. Approximately 600 patients use this facility.
- In Cork and in the D'Olier Street Blood Donation Clinic, clinical responsibility for the patient remains with the referring clinician. People who wish to use these services must get a prescription from their GP or hospital clinic on an IBTS form. The prescription is valid for one year and provides for up to four phlebotomies per person per year. There are no capacity issues in these clinics and it is hoped to build up the numbers further over time. By March 2016 1,417 patients were using the facility in Dublin and Cork: of these 679 (48%) had become blood donors.

The IBTS donor prescription form is available at:
https://www.giveblood.ie/Clinical_Services/Haemochromatosis/Donor-Prescription-Form.pdf

The IBTS report that uptake in the Cork and D'Olier Street practices is low due to a possible lack of knowledge of referring to these centres and the use of established hospital based clinics in the area.

Advantages and Disadvantages of the IBTS

- Advantages: Established track record with delivering phlebotomy services for HH patients in Dublin and Cork. The IBTS have experienced staff who regularly perform phlebotomy. The majority of patients would like to donate blood. Increase the IBTS national blood supply.
- Disadvantages: IBTS services for patients with HH are not yet available nationally which restricts access. Do not hold clinical responsibility of patients.

3. RECOMMENDED DELIVERY OF PHLEBOTOMY

3.1. INTRODUCTION

Once a patient has been diagnosed with Hereditary Haemochromatosis and the clinician has confirmed the patient fulfils the criteria for therapeutic phlebotomy, the patient can undergo/be referred on for phlebotomy. Patients should be able to move easily between registered phlebotomy providers. Patients should also have their own personal phlebotomy records which would facilitate their ongoing care.

The principles for the delivery of phlebotomy are based on both the interests of the patients and the interests of the HSE. From a patients perspective it is important to have ease of access to services, phlebotomy delivered safely and efficiently, a guarantee of quality of care and to be able to donate blood if wished. The HSE's perspective is to deliver a high quality and safe service that is undertaken efficiently, in the most cost effective way and at the lowest level of complexity. In addition, the health system, through the Irish Blood Transfusion Service (IBTS) has a legitimate need and social responsibility to maximise the supply and safety of blood donation, a central tenet of which is that donations are made freely and altruistically.

Blood donation

The EASL states that: '*blood taken from patients with HH at phlebotomy should be made available for national blood transfusion services for the public good, if there is no medical contraindication and the patient has given consent. It is recognized that many patients with HFE-HC will have clinical features that exclude them from being accepted as donors (elevated liver function tests, diabetes, medications). But in the absence of these, there appears to be no medical reason, other than administrative and bureaucratic, for why the blood taken may not be used. In Europe, the fact that the blood is being taken for therapeutic reasons should not be a hindrance to its utilization.*' (10).

The collection and transfusion of blood from people with HH is done in America, Canada, Australia and New Zealand but varies within Europe (10). In Europe, donor eligibility criteria are described in Commission Directive 2004/33/EC, implementing Directive 2002/98/EC of the European Parliament and of the Council. In detail, no specific criteria for neither carriers with a documented HFE mutation nor patients with HH are described in this Directive. However, a general statement concerning haematological and metabolic disease is listed (i.e. prospective donors with serious active, chronic, or relapsing haematological or metabolic disease are permanently deferred for allogeneic donations).

Recognising that HH subjects could constitute a safe source of blood for transfusion, the US Food and Drug Administration in 2001 issued guidance to allow blood from HH donors to be used for transfusion. The guidance had four major aims (a) the policy allowed the transfusion of blood from patients with hemochromatosis if the blood met all known safety standards; (b) the policy eliminated financial incentives for hemochromatosis patients to falsify responses to blood bank questions about health status and about possible behaviours that increased the risk of transmissible infections; (c) blood banks that accepted the blood for transfusion from any hemochromatosis patient were required to provide phlebotomy therapy without charge to all hemochromatosis patients who came to the blood bank; and (d) the policy authorised a blood bank to perform phlebotomy therapy according to the prescribing physician's written orders (11).

There are few studies reporting the percentage of HH patients that are eligible for blood donation. Leitman et al (12) reported that 76% of American patients with HH met eligibility criteria for blood donation. A New Zealand study showed the 53% of HH patients were eligible to donate (13).

Licencing of Blood Donation

The IBTS is a licensed Blood and Tissue Establishment by the Health Products Regulatory Body (HPRB) in Ireland. The EU Directive 2002/98/EC and associated Directives are applicable to the Blood Establishment. This directive seeks to ensure that blood is collected and tested only by designated, authorised, accredited or licensed establishments with suitably qualified personnel. Blood establishments must evaluate all blood donors, test each donation (to check if a donor has hepatitis B or C, for instance) and ensure proper storage, transport and distribution of the donated blood. Thus, blood from HH patients cannot be collected unless the establishment is accredited. *The IBTS is currently the only accredited body in Ireland for this i.e. only individuals working for the IBTS can collect blood.*

The IBTS have reported that for blood to be donated to the national blood supply in the community or hospital based phlebotomy clinic, due to strict licensing regulations, there would have to be a member of the IBTS staff present to carry this out. At the point where the patient decides to go ahead with phlebotomy they would be given the option of donating their blood. If they opt to donate then phlebotomy will be carried out by IBTS staff. Once the IBTS donation is complete the patient returns to the care of the HH clinic for follow up.

3.2. RECOMMENDED DELIVERY OF PHLEBOTOMY

Except in specified circumstances, phlebotomy does not need to be undertaken in a hospital. The procedure can, for the most part, be safely and effectively delivered in the community. There should be a range of providers according to geography, existing services and access to IBTS clinics.

The working group recommend, where permission has been granted by the patient and the patient fulfils safety standards, patients should be referred to IBTS where the service is available (see Section 2.1). This would increase supply for the IBTS for the public good.

The infrastructure is not currently in place nationally for all patients to donate to the IBTS and some patients may not wish to or may not be eligible for referral to the IBTS. Therefore, a number of community based locations should also be available for patients to undergo phlebotomy. These include:

- General Practitioner: GP surgery/Primary Care Centre/ GP Minor Surgery Network
- Community based nurse-led clinic e.g. Community Intervention Team (CIT). The clinic will liaise with the GP and/or relevant consultant in acute care who is responsible for the overall clinical management of patients with HH.

Where patients fulfil the referral criteria for specialist care, phlebotomy may be undertaken in acute care.

1) The Irish Blood Transfusion Service (IBTS)

As well as continuing their clinics in Stillorgan, D'olier Street and St. Finbarrs the IBTS is planning to introduce a mobile clinic model for HH patients in Limerick in 2016. If this model proves successful, the IBTS will consider rolling it out to all its mobile clinics. In this new model, people with haemochromatosis could attend a single regional centre for initial evaluation and treatment; if they wished to become blood donors they could go to any local IBTS mobile clinic to donate, returning to the fixed site regional centre whenever necessary (for example if temporarily ineligible because of travel restrictions on eligible blood donors).

The IBTS have agreed if the Limerick model works, mobile clinics could be opened in a few other major centres – Galway, Sligo, Cavan/Monaghan and the Midlands for example; at its simplest the IBTS would run a phlebotomy and assessment clinic once a month in each of these sites, and donors in the region would be able to go to ordinary IBTS blood collection clinics, non-eligible patients would be able to come back to the regional monthly clinic for treatment. The IBTS are also considering offering double-dose, machine-based collections to

reduce the number of clinic attendances that the donors need to make. This is called 'Double Red Cell Apheresis'. Clinical management of the patient will remain with the referring GP/Consultant.

Thus, all suitable patients should be referred onto the IBTS. The expansion of the IBTS nationally will increase the number of patients being referred. The IBTS will provide phlebotomy for patients with stable ferritin who meet the referral criteria whether they are eligible or non-eligible for blood donation.

With routine referral to the IBTS, treatment costs are minimised, phlebotomy therapy is performed by skilled staff in a highly regulated environment, and a collateral societal benefit may occur (14).

Recommendation:

I. **Support the expansion of the IBTS and recommend that patients with hereditary haemochromatosis are referred onto the IBTS (where the facility is available, patient consent has been gained and referral criteria is met). This would ensure an increase in the national blood supply.**
II. **The IBTS should explore opportunities to coordinate with primary care to facilitate the donation of blood in the community e.g. setting up mobile clinics within GP clinics/CIT clinics.**
III. **The IBTS should consider the use of Double Red Cell Apheresis as it achieves iron depletion in HH patients in a shorter treatment period than therapeutic phlebotomy.**

2) General Practice

The majority of patients can be effectively managed and undergo phlebotomy in a primary care setting.

Recommendations:

IV. **GP's should be supported and encouraged to provide phlebotomy services for patients with Hereditary Haemochromatosis.**
V. **The ICGP should develop a list of GP's who provide therapeutic phlebotomy. This should be made available online.**
VI. **Support the expansion of the GP Minor Surgery Network Pilot which provides therapeutic phlebotomy for HH patients (expansion to 60 locations in 2016). This network will be geographically diverse to ensure patients can have local access to such services.**

VII. **The standards being developed by the GP Minor Surgery Network (with regard to sterility, disposal of waste and credentialing process) should be extended for use by any GP practice who would like to undertake therapeutic phlebotomy for their patients.**

VIII. **Where feasible and where the IBTS service is not currently available in the area, GP's should coordinate with the IBTS to set up a mobile clinic to allow the donation of blood to the national blood supply.**

3) Nurse-led phlebotomy clinic in the community

Nurse-led phlebotomy clinics, currently run in hospitals, should be transferred to the community. These clinics could be carried by Community Intervention Teams (CIT). CITs are a nurse led service supported by a variety of other healthcare professionals and community services. CIT aims to provide enhanced short term acute interventions, in a rapid and integrated manner to a patient with an illness appropriate for care in the home/community. After referral by a GP/Consultant, the CIT will provide phlebotomy services according to the referral criteria. The care of the patient will be managed by the GP/Consultant who will conduct all necessary blood tests. The clinic will undertake the same activities as documented above in the hospital based clinic. This model encompasses a patient-centred approach with both treatment, education and lifestyle being addressed.

CIT services vary in terms of the length of time established. Not all services have a designated clinic space at present, however, this is being progressed.

Table 2. List of Community Intervention Teams, June 2016

CIT	Clinic Space
Dublin North	Yes
Dublin South	Yes
Kildare	No
Louth	No
Meath	No
Wicklow	Yes
Carlow / Kilkenny	Yes
Midwest (Limerick, North Tipperary, Clare)	Yes
Cork	Yes
Galway	No
Waterford	Yes
South Tipp (short term basis)	No

Recommendation:

IX. **Move hospital-based nurse-led phlebotomy clinics to the community e.g. service can be provided by Community Intervention Teams. The referring GP/Consultant is responsible for the overall clinical management of the patient.**

X. **Where feasible and where the IBTS service is not currently available in the area, CIT's should coordinate with the IBTS to set up a mobile clinic to allow the donation of blood to the national blood supply.**

4) Acute Care

Patients should be primarily managed in the community by their GP. It is envisioned that the GP will be actively involved in the diagnostic work-up for haemochromatosis. Patients need not be managed or receive therapeutic phlebotomy in an acute care setting unless they fulfil the criteria for hospital referral and intervention as outlined in the Model of Care for Hereditary Haemochromatosis (see Appendix 3).

Future care and phlebotomy requirements for patients who have been attending hospitals for their phlebotomies, could be transferred to the community if patients are deemed fit and fulfil the criteria for community level care.

Recommendation:

XI. **Patients should not be managed or receive therapeutic phlebotomy in an acute care setting unless they fulfil the criteria for hospital referral and intervention (Appendix 3).**

XII. **Future care and phlebotomy requirements for patients who have been attending hospitals for their phlebotomy, could be transferred to the community if patients are deemed fit and fulfil the criteria for community level care.**

Other Locations

There may be scope to develop other community based phlebotomy services not documented here.

Future potential development of the Individual Health Identifier (IHI) and a database for patients with Hereditary Haemochromatosis will facilitate patients moving between secure providers and enhance patient choice.

3.3. COSTING

The provision of phlebotomy and the cost to the patient needs to be addressed at policy level. Since 2014, the HSE has implemented a major change in the way hospitals are funded with the provision of Activity-Based Funding (ABF) formerly known as Money Follows the Patient. ABF means that hospitals are paid for the actual quantity and quality of care they deliver to patients. With this new way of funding being established, money following the patient from acute care to primary care should also occur. There is the potential difficulty of transferring patients from the acute setting (where some public patients currently receive phlebotomy free of charge) to the primary care setting where they may incur a cost to undergo phlebotomy. This may be financially prohibitive for some patients. In addition, those who qualify for a medical card receive phlebotomy treatment free of charge, but have to attend hospital for treatment as phlebotomy is not covered by the GMS (General Medical Service Scheme) if carried out in a GP surgery.

The above could lead to a situation where patients are reluctant to be transferred to the primary care setting. In addition there may be a financial incentive to inappropriately attend the IBTS. Proper steps need to be taken to remove incentives for incomplete risk disclosure and the IBTS should continue to provide phlebotomy therapy without charge to all hemochromatosis patients who meet their referral criteria regardless whether blood can accepted for donation.

Recommendation:

XIII. In order to effect the transfer of patients from the acute to primary care setting it is essential that the cost incurred by the patient is addressed at policy level.

4. SOP'S, PROTOCOLS AND GUIDELINES FOR PHLEBOTOMY

4.1. DEFINITION

Therapeutic phlebotomy for patients with Hereditary Haemochromatosis involves the removal of 400–500 ml of blood (200–250 mg iron). The procedure is similar to that of blood donation.

4.2. OBJECTIVE

- Fasting Serum Ferritin 50-100 µg/L.
- Fasting Transferrin Saturation <45%.
- Avoid anaemia:
    - Allow haematocrit/haemoglobin to fall by no more than 20% of prior level.

4.3. CRITERIA FOR PHLEBOTOMY

Patients are eligible for therapeutic phlebotomy for HH if they have HFE gene AND increased body iron stores (fasting SF: > 200 µg/L in pre-menopausal women and >300 µg/L in men and post-menopausal women AND Fasting TS ≥45%).

The patient should also have had a:

- Full Blood Count in past 3 months
- Liver Function test (serum AST and ALT activity)
- Fasting blood glucose level or Haemoglobin A1C (HbA1c)
- Documentation of any specific risks – HIV, Hepatitis, MRSA.

Patients who have fulfilled the criteria for secondary referral or have contraindications to phlebotomy, as detailed in the Model of Care for Hereditary Haemochromatosis document, should also be referred for specialist care in a hospital setting. Please see Appendix 3.

4.4. PHLEBOTOMY SCHEDULE FOR HEREDITARY HAEMOCHROMATOSIS

Clinicians must design phlebotomy treatment regimens that are individualised to each patient. When designing the regime the following patient factors need to be considered: age, gender, weight, general health and likelihood of compliance. Special precautions may need to be taken for patients on beta-blockers, as they may be susceptible to syncope (1).

1) Iron Unloading Phase

Iron unloading phase (1,14)
• Weekly phlebotomy of approximately 500 ml whole blood (or as tolerated by patients) until SF is <250 µg/L and then monthly until SF has reduced to < 50 - 100 µg/L. • Pre-phlebotomy haemoglobin should be >12.5 g/dL • Monitor haemoglobin every 4-6 phlebotomies. Delay for 1 week if pre-phlebotomy Hb <11 g/dL. • Monitor SF every 4-6 phlebotomies, until approaching target values (approx. 100 µg/L), then take on each occasion. Levels of SF less than 25 µg/L indicate iron deficiency and require a temporary hold on phlebotomy. Transferrin Saturation usually remains elevated until iron stores are depleted.
Note: it may take many months or even years to unload excess iron. Oral supplements for vitamin B12 (5 µg daily) and folate (500 µg daily) support erythropoiesis during frequent phlebotomy, especially if the vitamin B12 or folate levels are deficient.

It can be confidently assumed that excess iron stores have been mobilised when the serum ferritin drops to between 50 and 100 µg/L (2,15).

2) Maintenance Phase

Once the target range is reached, the patient should be assessed for whether they require maintenance phlebotomy. Not all patients with HH re-accumulate iron and, accordingly, they may not need a maintenance phlebotomy regime. Due to the variable rate of iron accumulation in HH, the frequency of maintenance phlebotomy among individuals.

Lifelong maintenance phase
• Phlebotomy to maintain SF ~50 – 100 µg/L. • Highly variable between individuals, often in the range 2-6 phlebotomies per year. • Check Hb and SF before every phlebotomy (do not perform if Hb <11 g/dL). • If patient is not undergoing phlebotomy monitor SF at least once a year.
Monitoring SF is the only way to ensure safe levels maintained within acceptable ranges.

4.5. POSSIBLE COMPLICATIONS

Possible complications during phlebotomy treatment include:

- haematoma;
- hypovolaemia;
- vasovagal syncope;
- venous scarring;
- phlebitis;
- adverse reaction to lignocaine if used.

Observe the patient at all times and if the patient becomes tachycardic, hypotensive, restless or clammy, stop the procedure and review patient. It is rare for patients not to tolerate phlebotomy therapy, unless in patients with severe cardiac disease, anaemia or hypoproteinaemia. These patients may be given chelation therapy (desferrioxamine) for the removal of iron – however this is costly and is rarely needed in practice.

Potential harm of frequent phlebotomy therapy for a person with normal serum ferritin or no iron overload include: the development of iron deficiency anaemia, reinforcement of a suboptimal management strategy for a biochemical abnormality, and the general phlebotomy risks of venous scarring, phlebitis and vascovagal episodes.

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4.6. PROTOCOL FOR PHLEBOTOMY

It requires around thirty minutes to undertake a phlebotomy.

Phlebotomy Procedure Prerequisites

- correct patient (check name and date of birth)
- confirmed diagnosis of HH
- stable **haemoglobin >12.5 g/dL**
- serum **ferritin above 25µg/L**
- stable blood pressure systolic 110-160mmHg, diastolic 60-95mmHg
- stable pulse 50-100/minute
- ability to appropriately dispose of collected blood (clinical waste/biohazard)
- venous access – usually cubital fossa of the opposite side from the most recent phlebotomy
- adequate pre-phlebotomy hydration
- check with the patient regarding recent oral intake, best if food is eaten two hours before procedure
- explain procedure to patient and ensure patient understands it
- consent has been obtained (both verbal and written)

Appropriate Clinical Environment

- The phlebotomy procedure should be taken in a dedicated location that ensures patient comfort and privacy
- The dedicated area should include:
    - clean surface with couch to tilt or lie patient flat
    - hand wash basin with soap, running water and paper towels
    - alcohol hand rub.
- Floors should not be carpeted.
- The workplace should be clean, tidy and uncluttered. There should be no sign of blood contamination.
- All clinical environmental areas should allow for easy cleaning i.e. wipeable surfaces.

Equipment

- Blood pressure monitor (with varying cuff sizes)
- Phlebotomy bag (e.g. 450ML blood bag with needle or needle free)
- Blood specimen vials
- Personal protective equipment (e.g. 2 pairs of well-fitting non-sterile gloves and apron)
- Clean single use tourniquet
- Alcohol swab or chlorhexidine in alcohol 2% as per local policy (for skin preparation)
- Topical anaesthetic agent if prescribed
- Sterile gauze squares/ Cotton topper balls / gauze swab (for application over the puncture set)
- Surgical Tape
- Stress ball or soft rolled bandage to squeeze
- Sharps Bin
- Placenta Bin
- Electronic scales to weigh blood bag if required
- A clean tray or trolley to should be used to lay out equipment

Example Procedure

1. Check patients fulfils all prerequisites listed above and has rested for 15 minutes immediately before phlebotomy.
2. Perform hand hygiene
3. Set up the equipment listed above.
4. Consult the patient as to any preferences in site and problems that may have been experienced on previous venepuncture. Then lie patient semi prone or prone with arm extended and resting comfortably.
5. Record resting blood pressure and pulse. The patient should be observed throughout the procedure for any signs of parasthesia, fainting or dizziness. The National Early Warning Score (NEWS) (16) should be used whenever possible (i.e. when the health care worker has been trained in its use).
6. Place plastic backed absorbent sheet under client elbow. If an electronic scales is being used place plastic backed absorbent sheet on it located approx. 30cm below client level.
7. Put on apron. Decontaminate hands using alcohol hand rub/gel, allow to dry. Apply gloves.
8. Apply a tourniquet 5-6 centimetres above the intended site. Ask the patient to clench their fist or place arm below heart level to encourage venous filling. Palpate the site to check for rebound elasticity – press lightly with two fingers and release.
9. Clean venepuncture area with skin disinfectant in a circular motion from insertion site outwards (5-10 cm diameter). Do not go back over previously cleaned areas. The alcohol washing may have to be repeated, depending on the cleanliness of the skin. Allow to dry for 30 seconds. Remember, if it is not dry, it is not sterilised. Do not touch the venepuncture area after cleansing.
10. Open and assemble the appropriate blood collection set. Attach the venepuncture needle to blood bag.
11. Insert needle (Using thumb of non-dominant hand, apply slight traction to the distal end of the vein to stabilise it. Determine where the bevel of the needle is. Turn the needle until the bevel is up in relation to the patient's skin. This will allow the sharp point of the needle to enter the skin first. The angle the needle is inserted at depends on the position of the vein. In prominent veins, use an angle of approx. 15 degrees. In deeper veins, an angle of approx. 45 degrees is used. Care should be taken not to enter too fast and too deep otherwise the needle can go through the back of the vein.)

12. Once the vein has been entered, secure with 2 strips of surgical tape (1 over tubing and 1 over needle insertion site). Place blood bag on electronic scales (if being used).
13. Release tourniquet slightly. Check frequently that blood flow into bag is continuing evenly and fairly slowly. Aim for a blood flow rate of 1 ml/sec.
14. If no sample can be obtained, remove the blood bag, remove the tourniquet, withdraw the needle and locate to another site. If no success after two attempts, seek further help from a more experienced person.
15. Hb and SF should be taken every 4-6 phlebotomies during treatment (iron unloading) phase or every phlebotomy during maintenance phase.
16. The phlebotomy should take 10-20 minutes. If necessary, instruct patient to gently squeeze a stress ball or soft rolled bandage in hand of arm undergoing phlebotomy.
17. Release tourniquet or cuff when bag is at ordered weight or once the desired ml have been obtained (typically no more than 500ml).
18. As you remove the needle, cover the site with cotton wool/gauze. Do not apply pressure until the needle is removed from the vein as this can cause unnecessary venous damage. Pressure on vein should be firm for 30-60 seconds to prevent bruising. The arm can be elevated while applying pressure to prevent haematoma formation but do not bend the arm. Then ask patient to apply pressure with the cotton wool/gauze. Where patients are taking anti-coagulants extra vigilance to be given in observing the site for evidence of bleeding or the formation of haematoma.
19. Dispose of needle safely as per sharps policy.
20. If blood is not being donated, discard blood as per local policies for blood products.
21. Apply sterile pressure dressing (or plaster) over the puncture site. Instruct patient to remain lying/sitting down for 15 minutes. Advise the patient not to perform heavy lifting with that arm and to avoid strenuous exercise for 24 hours. If patient feels faint or dizzy lie them flat and check their blood pressure (use of NEWS whenever possible).
22. Remove gloves and decontaminate (wash) hands
23. Offer the patient a drink and/or food and recommend they drink plenty of fluid over the next 24 hours.
24. Fill out patients phlebotomy record card including

- the patient's details, weight and concomitant conditions;
- alcohol use and BMI;
- details of the different health care professionals involved in care;
- blood pressure and pulse at each phlebotomy;
- blood collection dates and volumes/weight;
- results of serum ferritin and serum haemoglobin tests;

- a statement of the doctor's agreement concerning the phlebotomies and reasons for changes in treatment;
- a statement of any incidents and side-effects occurring during the phlebotomy procedure (safety);
- any patient education given.
- other investigations taken (e.g. biopsy, ECG).

25. Fill out the patient's personal record card. This contains less detail but enables the patient to personally monitor their iron status (Appendix 4).

Tips & Hints

- Generally all patients undergo phlebotomy of approximately 500mls. Exceptions include very slight patients who can only tolerate half a bag. Any deviations to volume should be recorded in the patient's medical notes.
- Develop an action plan for a patient if the needle has to be recited and if phlebotomy failure after two attempts
- Poor blood flow may be due to position of needle and/or inadequate hydration prior to phlebotomy.
- Repeated phlebotomies will cause scarring of the veins and thus difficulty accessing the vein. Try to rotate vein usage. Ensure location of phlebotomy needle is documented at each appointment.
- Patients may become faint during or after the procedure. Encourage good oral fluid intake in the 24 hours prior to phlebotomy and adequate time to recover.
- If patients have problems with blood pressure dropping after phlebotomy they should be referred on for phlebotomy in the acute setting.
- Patients who are needle phobic may require topical local anaesthetic cream to be applied 20-30 minutes before the procedure or use of ethyl chloride spray immediately prior to phlebotomy.
- The puncture site may start to bleed once the patient has left the clinic. Alert patient to this possibility and advise them to apply pressure and return to the department if it does not stop quickly.
- Advise the patient not to attend for Phlebotomy or have blood samples (e.g. full blood count, ferritin) taken if they have any acute infection i.e. cold, chest infection. Ferritin is an inflammatory marker and will rise temporarily when infection present.

For more information please refer to the 'World Health Organisation (WHO) guidelines on drawing blood: best practices in phlebotomy' found at http://www.who.int/injection_safety/sign/drawing_blood_best/en/.

5. WASTE COLLECTION PROTOCOLS AND INFECTION CONTROL

5.1. INFECTION CONTROL

The document 'Infection Prevention and Control for Primary Care in Ireland' (17) should be abided by which covers topics including:

- Hand hygiene;
- Personal protective equipment;
- Management of sharps and sharps injury;
- Decontamination of the environment;
- Management of spillages of blood and body fluids;
- Management of laundry;
- Safe management of healthcare risk waste.

All practices should abide by this document when undertaking phlebotomy and it can be accessed at the link: http://www.hpsc.ie/A-Z/MicrobiologyAntimicrobialResistance/InfectionControlandHAI/Guidelines/File,14612,en.pdf

5.2. WASTE STORAGE AND DISOPOSAL

Current Irish legislation places the primary responsibility for waste and its disposal on the producer i.e. general practitioner. Proper segregation, packaging, labelling, storage and transport of health care waste must be undertaken according to 'The Segregation, Packaging and Storage Guidelines for Healthcare Risk Waste' (DOHC, 2010). Colour coding is used in respect of all containers/bags used to hold healthcare waste prior to final disposal. Healthcare risk waste is coloured yellow.

Blood bags for disposal following phlebotomy are suitable for alternative technology i.e. steam sterilisation. As per the DoH Guidelines "bagged blood, blood products, and blood components" may be disposed of in a 30/60 litre yellow rigid bin with a yellow lid. However, in primary care due to the low volume generated, the available storage within GP surgeries and monthly risk waste collections these blood bags may be placed in a placenta bin with a red lid. This bin can take up to 5 bags and is a more suitable size for storage awaiting collection. The red lid denotes alternative technology disposal. The black lid placenta bins are used for the disposal of placentas and denotes treatment by incineration. These should not be used for phlebotomy bags.

Blood bags with needle have an integrated needle guard attached that when activated reduces the risk of needle stick injury following the procedure and also ensures that there is

no exposed needle when disposing of the equipment used. Health care workers should be educated on the proper use of this guard and it should not be removed.

Recommendation:

XIV. **Dispose of blood bags (with set attached and needle guard activated) by alternative technology. Suitable packaging options include either a 30/60 litre yellow rigid bin with yellow lid (with absorbent material) or a placenta bin with a red lid. Check your local waste collection contractor to clarify the appropriate bin.**

5.3. ADDITIONAL INFORMATION

Please note the following may have changed since the publication of this document:

Yellow risk waste containers

Available from the following companies:

The Patron Group 81 Baldoyle Industrial Estate Baldoyle Dublin 13 Tel: 00353 1 8391299 Fax: 00353 1 8291026 www.patron.ie	Homecare Medical Supplies, Tooraree, Knock Rd, Ballyhaunis, Co.Mayo W: www.homecaremedicalsupplies.ie T: +353 (0)94 9633800

Collection and Disposal

There are no standard national arrangements for collection of healthcare risk waste at present. In some areas it is provided by the HSE, in others the GP arranges the collection themselves. The HSE has a clinical waste contract for its different locations. GPs can avail of the contract, but approval is required to activate the contract for them. Certificates of collection, export and disposal should be provided by the healthcare risk waste contractor.

Collection of full yellow containers is by hazardous waste permitted companies. These companies are permitted by the National Waste Collection Permit Office (operated by Offaly County Council on behalf of all Local Authorities; contact NWCPO Tel: (057) 9357428 or email contactus@nwcpo.ie) as hazardous waste collection permits are required to collect hazardous healthcare risk waste. These companies also supply consumables i.e. yellow risk waste containers on an exchange basis.

Four permitted companies:

1. Clinical Collections Ltd., O41 9845352
2. Initial Medical Services. 1800 303 268
3. OCS Ltd., 1850 67 57 47
4. SRCL Ltd., Tel: 01 6166906

Copies of their Waste Collection Permit should be obtained by the GP Surgery.

Certificates of Destruction

SRCL Ltd. is the only EPA licensed hazardous waste company in Ireland that can treat hazardous healthcare (risk) waste. Charge is on a price per weight basis.

6. CLINICAL GOVERNANCE

6.1. QUALITY AND PATIENT SAFETY

Responsibility

It is the responsibility of the health care worker to ensure that the procedure is carried out correctly, competently and strictly according to the phlebotomy clinic clinical guideline and in accordance with their professional accountability and scope of practice.

Safety

- Under the Health and Safety Act 2005, employees must ensure that they wear personal protective clothing where necessary and not do anything which would place themselves or others at risk.
- Care should be taken to prevent needle stick injuries when using and disposing of sharps.
- The user of sharps is responsible for their appropriate use and disposal. Sharps should never be left in a work area for a colleague to dispose of
- All used disposable sharps should be discarded directly into sharps container
- Care should be taken to avoid spillages of blood while performing phlebotomy. In the event of a blood spillage, use appropriate PPE. Use an absorbable material to contain the spillage, then apply chlorine releasing compound at 10,000ppm. After 3-5 minutes collect/scoop all contaminated waste and discard into healthcare risk waster.

6.2. EDUCATION AND COMPETENCY REQUIREMENTS

Education

The working group recommend that health care workers undertaking phlebotomy for patients with Hereditary Haemochromatosis should be aware of the following:

- An overview of Haemochromatosis, and rationale for phlebotomy.
- Venous Site Selection
    - Structure of Veins
    - Anatomy of Veins, Nerves and Arteries
    - Selection of a Venous Site
    - Clinical Assessment to Choose a Vein
- Preparation for Procedure
    - Hand Hygiene

    - Describe the importance of ANTT and skin antisepsis
    - Personal Protective Equipment
    - Management and Disposal of Sharps
    - Blood Borne Viruses
    - Choosing appropriate equipment
- Procedure
    - Indications for Procedure
    - Communication
    - Consent
    - Topical Anaesthetic Agents
    - Pain relief if required
    - Skin antisepsis
    - Tourniquet Use and Application
    - Standard Equipment for Procedure
    - Demonstration of simulated venesection procedure
    - Venesection supervision /documentation of competencies
- The legal and professional issues associated with performing phlebotomy.
- Identify potential complications associated with phlebotomy and take appropriate action to prevent these complications
- Management of complications.
- All health care workers undertaking phlebotomy must be trained in infection prevention and control procedures.
- Documentation.

Training and Competency

The health professional must show competency in venepuncture as per HSE policies for each health care worker. These are different depending on whether the person is a nurse, phlebotomist or doctor. The HSE has produced the Guiding Framework for Education, Training and Competence Validation in Venepuncture and Peripheral Intravenous Cannulation for Nurses and Midwives (18). Nurses should abide by this policy when undertaking phlebotomy. Registered Doctors should ensure they are competent in phlebotomy before undertaking the procedure. The IBTS have their own policies and procedures which should be adhered to by all health care workers undertaking phlebotomy as part of the IBTS.

In general, it is recommended by the working group that if a registered nurse or doctor is undertaking phlebotomy for patients with HH they must be able to:

- Demonstrate understanding of the knowledge and skills necessary to perform therapeutic phlebotomy.
- Demonstrate understanding of their accountability and responsibility for their practice.
- Explain the anatomy and physiology in relation to therapeutic phlebotomy.
- Demonstrate knowledge of related health and safety regulations, infection control and standard precautions in relation to therapeutic phlebotomy.
- Explain the safe use of associated equipment.
- Describe potential complications of the procedure and remedial action to be taken.
- Maintain clear and accurate records of the procedure.

Competency Assessment

In line with current HSE policies, the working group recommend that 5 assessments of clinical competence in phlebotomy should successfully be completed on separate occasions. These assessments must be signed on each occasion by the assessor. The assessors must have completed training and gained competence in phlebotomy and be undertaking the procedure on a weekly to two weekly basis (See Appendix 5 for Example Competency Assessment).

This is an example competency assessment and can be adapted to local policies and procedures. *HSE policies and procedures for venepuncture should always be abided by each health care professional.*

6.3. AUDIT

The HSE recommends that at least 2 audits per service per year should be undertaken (19). 'A Practical Guide To Clinical Audit' by the Quality and Patient Safety Directorate, HSE (20) should be referred to before undertaking an audit.

1) Patient Safety and Satisfaction

The culture of patient safety and satisfaction is imbedded in healthcare. According to the National Standards for Safer Better Healthcare (HIQA) service users must be 'treated with kindness, consideration and respect and have the information they need to make decisions' (21). Formal consideration of patient's needs and preferences inform healthcare providers when planning and delivering a service. In order to continually improve services it is important to include feedback from patients. Phlebotomy clinics should use validated surveys on patient satisfaction and areas of improvement.

The document 'Using patient feedback to improve healthcare services' by the HSE should be followed when developing patient surveys. To be found at: https://www.hse.ie/eng/services/yourhealthservice/hcharter/ask/feedbackstaffguide.pdf

2) Infection Protection and Control

It is advised that all Phlebotomy Clinics refer to the HSE document 'Infection Prevention and Control for Primary Care in Ireland' (17) which contain SARI (Strategy for the Control of Antimicrobial Resistance in Ireland) Infection Prevention and Control Audit tools for:

- clinical environment;
- hand hygiene;
- safe handling and disposal of sharps;
- decontamination of patient equipment;
- waste.

7. APPENDICES

APPENDIX 1. ACKNOWLEDGEMENTS

Working Group

Dr. Colm Henry	National Clinical Advisor and Group Lead Acute Hospitals
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Dr. Gerard Boran	Consultant Chemical Pathologist
Joe Ryan	Acting Head of the Programme for Health Service Improvement

APPENDIX 2. TONY FINCH REPORT ON HAEMOCHROMATOSIS NOVEMBER 2008

Introduction

The Irish Blood Transfusion Service (IBTS) oversees the collection of approx. 3000 units of blood on a weekly basis and supplies the blood and blood products to hospitals and special clinics throughout the country on a daily basis. Occasionally demand for blood outstretches availability e.g. bank holidays, Christmas, summer holidays etc.

Currently, blood taken from patients with Hereditary Haemochromatosis (HH) is not routinely made available to the IBTS for therapeutic use. There is no biological or medical reason for this. Many patients with HH have agreed that they would consider donating blood to the IBTS. The Irish Haemochromatosis Association (IHA) represents the interests of many patients with HH.

Aim

1. To ascertain if people with HH would consider participating in a donor / transfusion programme.
2. To examine the financial and management implications of blood collection and transfusion of a unit from people with HH within the Irish Healthcare System.

Background

There is a generic predisposition of 1:80 for HH in the Irish population (i.e. approx. 56,000). However, not all will develop the condition. It is estimated that approx. 18,000 patients are currently undergoing treatment for this condition.

HH is caused by excessive absorption of iron and a progressive increase in the total body iron content. This disorder can have life threatening complications such as liver cirrhosis, diabetes and heart failure. If untreated, the risk of mortality increases after the age of 45 in men and 55 in women.

The morbidity and mortality of HH can be reduced by early diagnosis and treatment to remove excess iron from blood. This procedure is referred to as phlebotomy or phlebotomy and involves the removal of blood from patients with HH at intervals depending on the severity of the condition.

Patients with a Serum Ferritin (Fe) level less than 500ng could donate every two weeks to reduce the Fe level to 50ng. It normally takes 20 – 30 units to achieve this level. Thereafter the patients can be placed on a maintenance programme that requires 4 – 6 units per year to be removed in order to maintain the 50ng level.

Collecting and transfusing blood from patients with HH is currently practiced in several E.U. countries and also in the USA, Canada, New Zealand and Australia. In these countries it is allowed under National Directives without any special conditions.

In Ireland it is not current practice for patients with HH to offer blood from phlebotomy procedures for transfusion, subject to the usual donor criteria. There is no biological reason for excluding this donor population from offering blood for donation to the Irish Blood Transfusion Service (IBTS) for therapeutic use.

Over 25,000 units of Red Blood Cells (RBC) were discarded in 2007 and it is anticipated that this number will increase due to treatment / awareness of this programme. These donors could also be used as a source of platelets once the RBC programme is up and running. Theoretically, this donation pool could represent 10% - 15% of the total altruistic donations taken by the IBTS.

A recent questionnaire to 250 HH patients gave the following information:-

1. 75% of patients receive treatment at a hospital clinic and ~20% attend a GP

2. The average return distance from home to receive treatment is 30 Km

3. 90% of patients would be prepared to travel to a specialist donor/transfusion clinic even if it involved extra distance or time.

4. Access to specific healthcare workers e.g. nurses / doctors is the most important criteria in choosing a donation site.

5. The costs for carrying out the phlebotomy is paid for by:-

   a). Government levy payment €60 - ~ 65% of patients

   b). Private health insurance ~ 35% of patients - Approx. €2.5 million is paid

   Out annually for the procedure and bed for the day.

   (Only used for approx. 1 hour)

   Note: Mater private charge €600 for bed and phlebotomy with additional charge for consultant.

Summary

Blood donation from people with HH could significantly increase the amount of blood / blood products available for medical use in this country. People with HH could be positively disposed to the establishment of donor / transfusion clinics. Donations must be made on an altruistic basis.

APPENDIX 3. SPECIALIST REFERRAL AND CONTRAINDCIATIONS TO PHLEBOTOMIES

Criteria for Hospital Referral and Intervention

Patients with the following should be referred on to the acute setting i.e. Gastroenterology/Hepatology:

- Patients with SF >1000 µg/L;
- Patients with cirrhosis/advanced liver disease;
- Patients with abnormal liver function tests;
- Patients with non-HFE iron overload;
- Patients who have contraindications to phlebotomies (both permanent and transient contraindications) or who have technical difficulties with phlebotomy;
- Diagnostic dilemma
- Patients with significant co-morbidities e.g. fatty liver disease.

Please note, the above is not obligatory criteria. If a clinician is unsure of the diagnosis or treatment of a patient specialist referral should be obtained.

Contraindications

Permanent and temporary or transient contraindications are given below in Table 3, based on 'Management of patients with HFE-related haemochromatosis (Type 1 haemochromatosis)' (22).

Table 3. Contraindications to phlebotomy

Permanent contraindications
• any disease likely to compromise the patient's health during phlebotomy • sideroblastic anaemia or any other form of anaemia caused by inadequate haemoglobin production and not by deficiency • thalassaemia major • severe or uncontrolled heart disease not secondary to haemochromatosis

- unstable or severe coronary disease, severe cardiomyopathy, left heart valve disease, uncontrolled heart failure, poorly-tolerated ventricular or supraventricular arrhythmias, etc. (a cardiologist should be consulted to establish the severity of the disorder).

Temporary and/or transient contraindications

- major iron deficiency anaemia (< 11 g/dL, particularly when this may be the result of previous phlebotomies)
- hypotension (SBP < 100 mmHg)
- severe occlusive arterial disease of the lower limbs, history of acute thrombotic ischaemia of a limb artery, or recent stroke (< 6 months)
- heart rate < 50 or > 100 bpm
- pregnancy (there is no major risk in suspending treatment for 9 months; during the 6 months following delivery, the reference serum haemoglobin threshold for blood donations is proposed to be 12.5 g/dL
- if the veins of the upper limbs are in very poor condition or inaccessible
- intercurrent disease leading to deterioration in general health.

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LOUTH COUNTY HOSPITAL DUNDALK

DAY SERVICES UNIT

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Venesection Record

HAEMOCHROMATOSIS

For further information
and support contact

THE IRISH HAEMOCHROMATOSIS ASSOCIATION

The Carmichael Centre
North Brunswick Street
Dublin 7

e-mail: irhaem@hotmail.com
http:/www.haemochromatosis-ir.com

Name .....

Address .....

.....

.....

Consultant

Dr .....

Address .....

.....

.....

Tel. ( ) .....

Signature

General Practitioner

Dr .....

Address .....

.....

Tel. ( ) .....

Signature

Venesection guidelines and goal.

*To be set by Medical Specialist/Practitioner

	Current	Maintenance
Haemoglobin (Hb)		
Serum Ferritin (SeFn)		
Transferrin Saturation (TS)		

Please ensure that you eat a good breakfast and drink plenty of fluids on the morning of your venesection.

DATE	AMOUNT	Hb	SeFn	TS	COMMENTS AND OTHER TEST RESULTS

Whilst on weekly venesections Hb should be checked each time.

DATE	AMOUNT	Hb	SeFn	TS	COMMENTS AND OTHER TEST RESULTS

DATE	AMOUNT	Hb	SeFn	TS	COMMENTS AND OTHER TEST RESULTS

DATE	AMOUNT	Hb	SeFn	TS	COMMENTS AND OTHER TEST RESULTS

Hints & Tips

Before venesection.

- Eat a well balanced diet at all times, and drink lots of water and fluids (not alcohol) before appointment time. The increase in fluid intake assists in better flow of blood at the time.

If veins are difficult to access then a hot pack may be beneficial. Some pumping up of the cardiovascular system by vigorous exercise. (Say, a brisk walk for 10 minutes or tackle a flight of stairs before treatment works well.)

After venesection.

- Keep an eye on your dressing for bleeding or unusual swelling or pain for 24 hours.
- Rest immediately after treatment for at least 15 minutes.
- Avoid carrying heavy objects with your arm for 24 hours.
- Avoid smoking or drinking alcohol for at least an hour after treatment.
- Eat regular meals and increase fluid intake to 2 - 3 litres per day.
- Wait until at least one day after treatment before playing vigorous sport, exercise or heavy work.

Note: *Approximately 450 - 500mls of blood is taken, which is about 7 - 9% of the blood volume of an average adult. This volume will be replaced by your body within 24 - 48 hours by drinking extra fluids. Tea, coffee, soft drinks are counted as fluids.*

APPENDIX 5. EXAMPLE PHLEBOTOMY RECORD OF SUPERVISED PRACTICE AND COMPETENCE ASSESSMENT FOR HEREDITARY HAEMOCHROMATOSIS

Please note that HSE policies and procedures should be abided by. This is an example HH competency assessment

Name of Phlebotomist: _____ Date: _____

The following areas must be examined on 5 separate occasions and the phlebotomist must demonstrate competence to being signed off by the assessor.

Competency Item		1	2	3	4	5
Correct Preparation of Equipment	Blood pressure monitor					
	Phlebotomy bag (including blood collection bag, collecting set needle and sampling port)					
	Personal protective equipment (gloves and apron)					
	Clean Single Use Tourniquet					
	Alcohol swab					
	Gauze squares/ Cotton wool					
	Sharps Bin					
	Electronic scales if required					
Correct Preparation of Environment	Good lighting					
	Patient sitting/lying position					
	Ensure workspace is clean and organised					
Prevention of infection	Perform hand hygiene as per WHO 5 moments for hand hygiene					
	Clean site with alcohol swab					
	Use PPE (gloves/apron)					
	Follow clinic infection control guidelines					
Ensure patient fulfils phlebotomy perquisites	Blood pressure					
	Heart Rate stable					
	Patient hydrated and recent oral intake					
	Blood count results acceptable for phlebotomy					
Introduce self to patient						
Identify patient. Patient must state name and date of birth and any allergies the patient has e.g.to tape or skin cleaning solutions						
Gain written consent						
Ensure patient has a clear understanding of the procedure						
Demonstrates the ability to identify a suitable vein for a safe phlebotomy procedure						
Demonstrates correct technique in skin cleansing, safe needle insertion and connection to appropriate equipment. Completes venepuncture procedure correctly and safely.						
Understands the need for obtaining correct volume/weight of blood for procedure						
Demonstrates appropriate troubleshooting techniques if required						
Demonstrates aseptic non touch technique, throughout the procedure						
Demonstrates disposal of sharps and equipment correctly and safely						

Demonstrates appropriate decontamination of equipment used (as per IP&C)						
Applies appropriate dressing over phlebotomy site following procedure						
Follows up with clinical observations						
Advises patient of immediate follow up care						
Records information correctly in patient's record card including reporting effectively any adverse reaction recognised (as per healthcare organisation policy)						
Other knowledge requirement	Explain the anatomy and physiology in relation to therapeutic phlebotomy					
	Describe potential complications of the procedure and remedial action to be taken					

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