# Results: large variability in policies

| Are some carriers/patients with HC accepted as blood donors ? | Are carriers/patients with HC allowed to donate more frequently then regular donors? | The location (country) where the surveyed blood service is located in. |
|---|---|---|
| YES | YES | Australia, England (UK), France, Republic of Ireland, Northern Ireland (UK), Norway, USA** (Portland [OR]) |
| | NO | Austria, Canada (Ottawa and Montréal), Czech Republic, Finland, Germany, Italy, Israel, Malta, Scotland (UK), South Africa, Sweden (Uppsala), Switzerland, The Netherlands, Wales (UK) |
| NO | | Belgium, Denmark, Estonia, Hong Kong, Iceland, Latvia, Luxembourg, Portugal, Romania, Slovenia, Sweden (Skåne) |

# Results: link between policy and prevalence

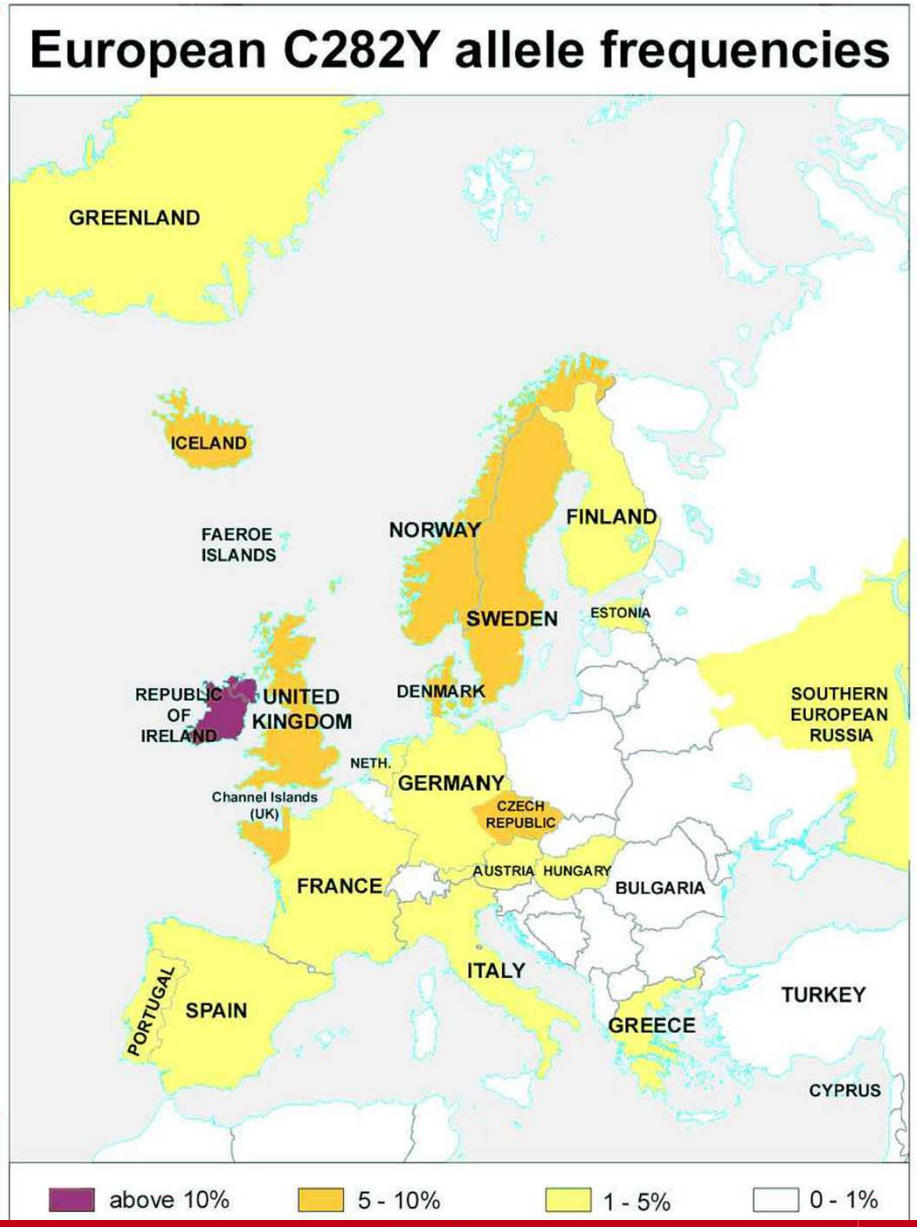
- Conclusions: **in general**
  - High allele frequency

    ↓

    Policy: eligible as donor
  - Low allele frequency

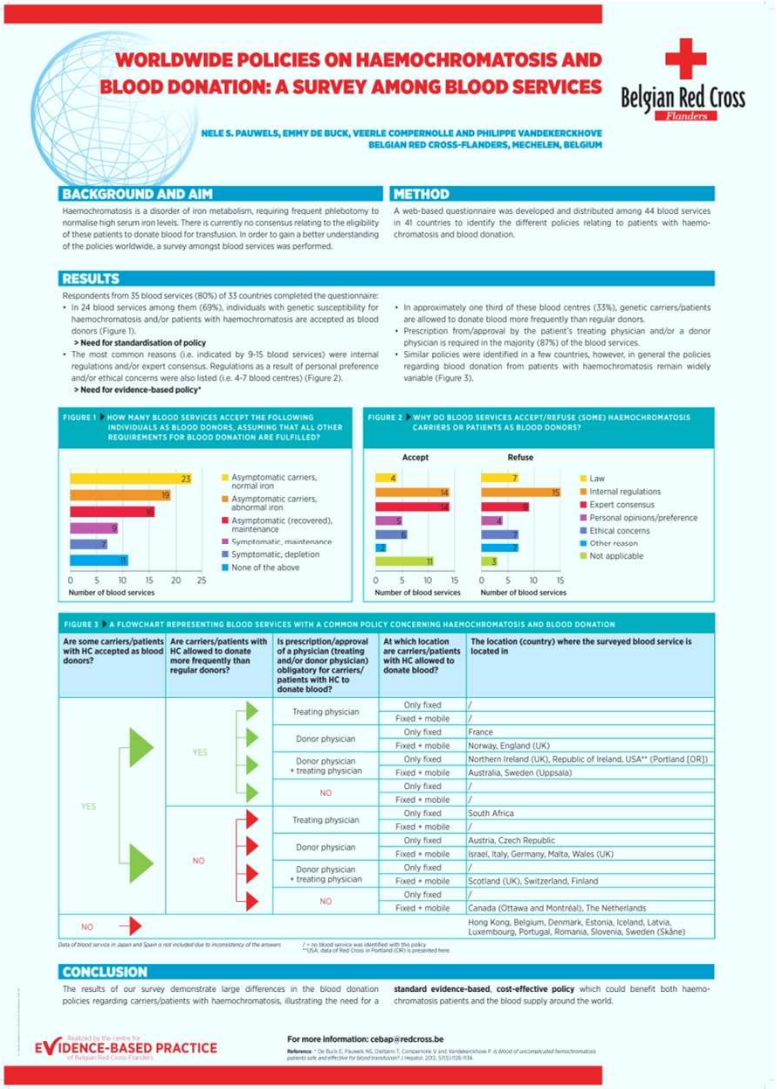
    ↓

    Policy: **not** eligible as blood donor




Merryweather-Clarke A. 2000

# Poster presentation



## WORLDWIDE POLICIES ON HAEMOCHROMATOSIS AND BLOOD DONATION: A SURVEY AMONG BLOOD SERVICES

Belgian Red Cross Flanders

NELE S. PAUWELS, EMMY DE BUCK, VEERLE COMPERNOLLE AND PHILIPPE VANDEKERCKHOVE
BELGIAN RED CROSS-FLANDERS, MECHELEN, BELGIUM

### BACKGROUND AND AIM

Haemochromatosis is a disorder of iron metabolism, requiring frequent phlebotomy to normalise high serum iron levels. There is currently no consensus relating to the eligibility of these patients to donate blood for transfusion. In order to gain a better understanding of the policies worldwide, a survey amongst blood services was performed.

### METHOD

A web-based questionnaire was developed and distributed among 44 blood services in 41 countries to identify the different policies relating to patients with haemochromatosis and blood donation.

### RESULTS

Respondents from 35 blood services (80%) of 33 countries completed the questionnaire:

- In 24 blood services among them (69%), individuals with genetic susceptibility for haemochromatosis and/or patients with haemochromatosis are accepted as blood donors (Figure 1).
  **> Need for standardisation of policy**
- The most common reasons (i.e. indicated by 9-15 blood services) were internal regulations and/or expert consensus. Regulations as a result of personal preference and/or ethical concerns were also listed (i.e. 4-7 blood centres) (Figure 2).
  **> Need for evidence-based policy***
- In approximately one third of these blood centres (33%), genetic carriers/patients are allowed to donate blood more frequently than regular donors.
- Prescription from/approval by the patient's treating physician and/or a donor physician is required in the majority (87%) of the blood services.
- Similar policies were identified in a few countries, however, in general the policies regarding blood donation from patients with haemochromatosis remain widely variable (Figure 3).

FIGURE 1 ▶ HOW MANY BLOOD SERVICES ACCEPT THE FOLLOWING INDIVIDUALS AS BLOOD DONORS, ASSUMING THAT ALL OTHER REQUIREMENTS FOR BLOOD DONATION ARE FULFILLED?




FIGURE 2 ▶ WHY DO BLOOD SERVICES ACCEPT/REFUSE (SOME) HAEMOCHROMATOSIS CARRIERS OR PATIENTS AS BLOOD DONORS?




FIGURE 3 ▶ A FLOWCHART REPRESENTING BLOOD SERVICES WITH A COMMON POLICY CONCERNING HAEMOCHROMATOSIS AND BLOOD DONATION

| Are some carriers/patients with HC accepted as blood donors? | Are carriers/patients with HC allowed to donate more frequently than regular donors? | Is prescription/approval of a physician (treating and/or donor physician) obligatory for carriers/ patients with HC to donate blood? | At which location are carriers/patients with HC allowed to donate blood? | The location (country) where the surveyed blood service is located in |
|---|---|---|---|---|
| YES | YES | Treating physician | Only fixed | / |
| | | | Fixed + mobile | / |
| | | Donor physician | Only fixed | France |
| | | | Fixed + mobile | Norway, England (UK) |
| | | Donor physician + treating physician | Only fixed | Northern Ireland (UK), Republic of Ireland, USA** (Portland [OR]) |
| | | | Fixed + mobile | Australia, Sweden (Uppsala) |
| | | NO | Only fixed | / |
| | | | Fixed + mobile | / |
| | NO | Treating physician | Only fixed | South Africa |
| | | | Fixed + mobile | / |
| | | Donor physician | Only fixed | Austria, Czech Republic |
| | | | Fixed + mobile | Israel, Italy, Germany, Malta, Wales (UK) |
| | | Donor physician + treating physician | Only fixed | / |
| | | | Fixed + mobile | Scotland (UK), Switzerland, Finland |
| | | NO | Only fixed | / |
| | | | Fixed + mobile | Canada (Ottawa and Montréal), The Netherlands |
| NO | | | | Hong Kong, Belgium, Denmark, Estonia, Iceland, Latvia, Luxembourg, Portugal, Romania, Slovenia, Sweden (Skåne) |

Data of blood service in Japan and Spain is not included due to inconsistency of the answers

/ = no blood service was identified with this policy
**USA, data of Red Cross in Portland (OR) is presented here.

### CONCLUSION

The results of our survey demonstrate large differences in the blood donation policies regarding carriers/patients with haemochromatosis, illustrating the need for a **standard evidence-based, cost-effective policy** which could benefit both haemochromatosis patients and the blood supply around the world.

Realized by the centre for EVIDENCE-BASED PRACTICE of Belgian Red Cross-Flanders

For more information: cebap@redcross.be

Reference * De Buck E, Pauwels NS, Dieltjens T, Compernolle V and Vandekerckhove P. Is blood of uncomplicated hemochromatosis patients safe and effective for blood transfusion? J Hepatol. 2012; 57(5):1126-1134.

# QUESTION 2

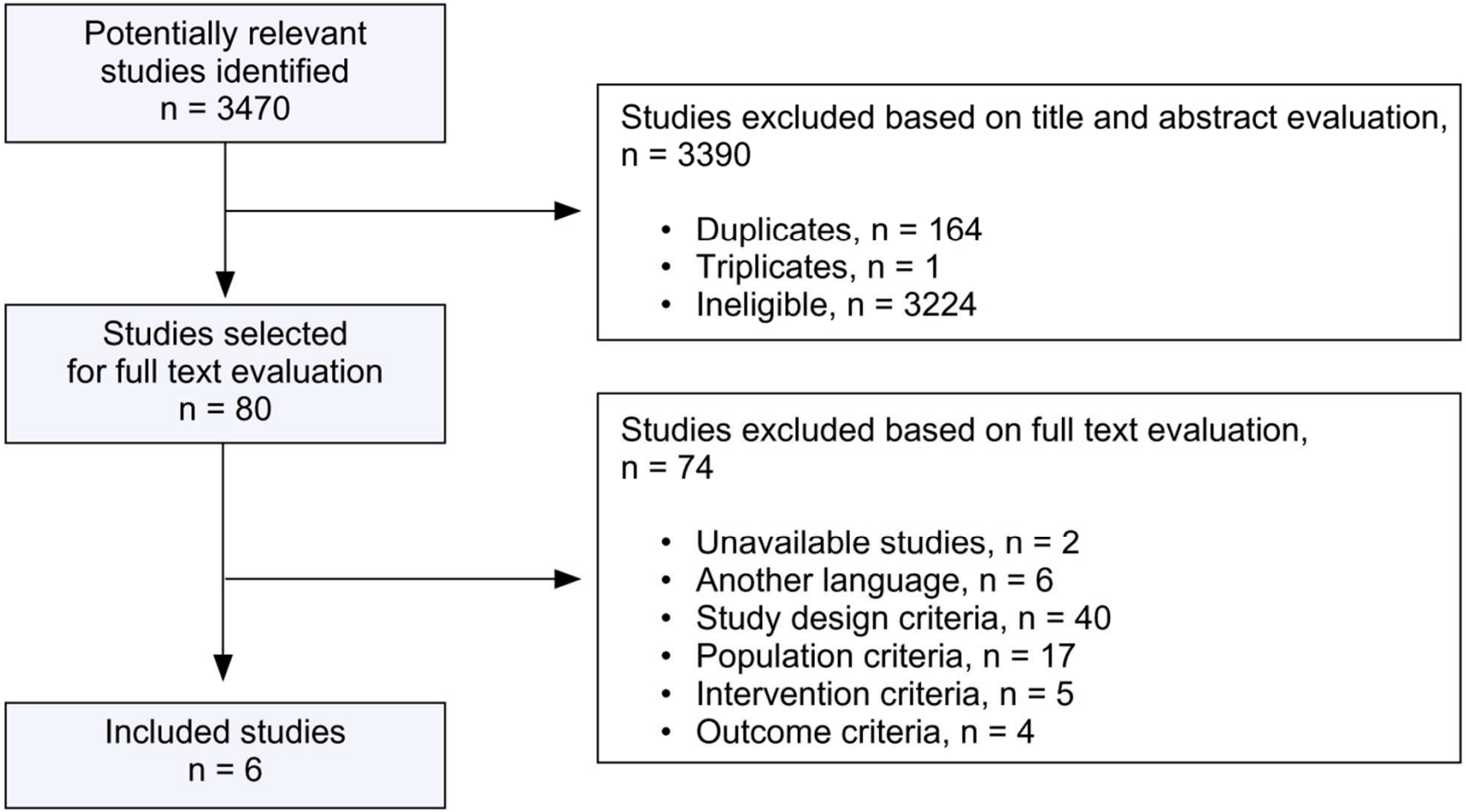
Is blood of **uncomplicated** haemochromatosis patients safe and effective for blood transfusion?

# Systematic review: methodology

- 3 pillars of EBM


- Cochrane Collaboration methodology
- 2 independent reviewers
- *Sources*: The Cochrane Database of Systematic Reviews, MEDLINE, Embase
- *Types of studies*: Randomized controlled trials (RCTs), controlled clinical trials, cohort studies, case-control studies, case-series, *in vitro* studies
- *Quality assessment* of the evidence: GRADE approach

# Systematic review: study selection



# Systematic review: results

- 6 observational studies
- Strength of the body of evidence: low to very low (because of limitations in study designs)


- No evidence could be found that shows that the blood from haemochromatosis patients would be of insufficient quality or would unsafe to be used for blood for blood transfusion.

# Haemochromatosis: daily practice

- Haemochromatosis blood is currently being used for transfusion without reported adverse effects
  - Unknown carriers who are donors
  - Link between policy and prevalence


- The voluntary character of the donation is guaranteed if phlebotomies are always performed, using the donor medical questionnaire in a rigorous way

# Haemochromatosis: preferences

- Including these patients into the donor pool is
  - preferred by **haemochromatosis patients** and **hepatologists**
  - relevant for the quality, convenience and cost of therapy

# Systematic review

**Published in J. of Hepatology**

Review

EASL EUROPEAN ASSOCIATION FOR THE STUDY OF THE LIVER | JOURNAL OF HEPATOLOGY

# Is blood of uncomplicated hemochromatosis patients safe and effective for blood transfusion? A systematic review

Emmy De Buck*, Nele S. Pauwels, Tessa Dieltjens, Veerle Compernolle, Philippe Vandekerckhove

*Belgian Red Cross-Flanders, Motstraat 40, B-2800 Mechelen, Belgium*

## Summary

Hemochromatosis is a disorder of the iron metabolism, characterized by high body iron content, necessitating frequent phlebotomies to remove excess iron. In some countries, this blood is discarded and not used for blood transfusion because of the non-voluntary character of this donation, and because a potential risk of microbial contamination of the donor blood is assumed.

A systematic review was performed in order to collect and critically examine solid evidence with regard to the effectiveness and safety of blood for transfusion when derived from hemochromatosis patients who do not suffer from complications or organ damage. Using three databases (The Cochrane Library, MEDLINE, and Embase) we searched for studies from date of inception until

## Introduction

Hemochromatosis is characterized by entry of iron into the blood stream in excess of that required for erythropoiesis. The excess iron can accumulate in parenchymal cells of liver, heart, endocrine glands, and other tissues, and result in organ damage. Hemochromatosis is in most cases inherited ('primary or hereditary hemochromatosis') as an autosomal recessive disorder, but can also be acquired. It arises from alterations in genes that regulate the synthesis of hepcidin, the latter downregulating the entry of iron into the blood stream, and many genotypes exist. Approximately 12.5% of individuals of Northern European descent are heterozygous for a mutation in the *HFE* gene (High Fe) and almost one in two to three hundred white people are homozygous. Based on genetic testing, it

# Haemochromatosis: conclusion

- Evidence + daily practice + preferences: there is **no scientific reason supporting the exclusion of these patients from the donor poc**


- Call for **standardisation** concerning the use of blood of uncomplicated haemochromatosis patients with normal iron levels

  ⇒ beneficial for patients

  ⇒ beneficial for blood services