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# SCREENING ALLOGENEIC BLOOD DONORS FOR PULSE RATE ABNORMALITIES: DOES IT PREVENT CARDIAC ISCHEMIC EVENTS?

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# Background

- Measuring the pulse rate of prospective blood donors: an inconsistent practice worldwide
  - In the United States:
    - Required for source plasma donors (CFR 21, Pt. 640.63)
    - Part of the 2007 proposed FDA Requirements for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing
    - Not required by the AABB standards
  - Elsewhere:
    - Not required by the European Directive (2001/98/EC)
    - However, 'normal' pulse rate specifications included in the Guide to preparation, use and Quality Assurance (Council of Europe)
    - Practice varies between European countries (Transfus Med Rev. 2009;23:205-20)
- No published evidence for or against the effectiveness of deferrals of donors who do not have a "normal" pulse rate

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# Background

- **Until 2007**: Héma-Québec temporarily deferred donors who had an abnormal pulse rate:
  - Less than 50/min (in a non-athlete)
  - Over 100/min
  - Irregular
- **Since 2007**: Pulse rate is assessed but donors are no longer deferred if the pulse rate is abnormal

## The study question:

**Is the risk of cardiac ischemic events reduced in donors with an abnormal pulse who are temporarily deferred, compared to donors with an abnormal pulse who are allowed to donate?**

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# Study design

- ‘Before and after’ retrospective cohort study of donors with an abnormal pulse rate
- Historical cohort of donors who were temporarily deferred
- More recent cohort of donors who were allowed to donate
- Comparison of rates of hospitalisation or death from cardiac ischemia during a **one-year** period following the abnormal pulse measurement
- Follow-up of donors through administrative health records

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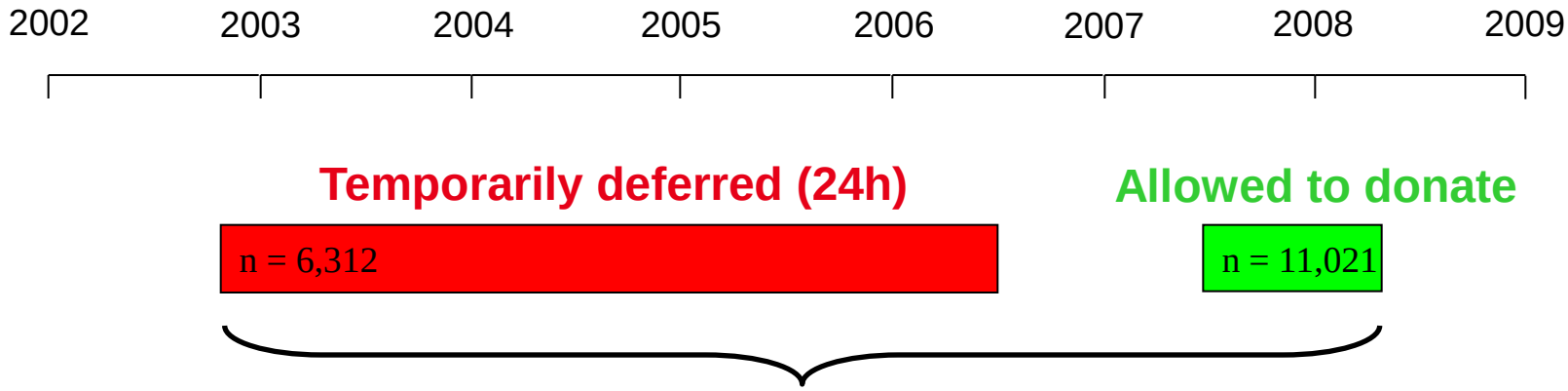
# Study population:




## Donors with an 'abnormal' pulse rate:

- **Below 50 bpm (in non athletes), or;**
- **Over 100 bpm, or;**
- **Irregular**

- Date of change in deferral policy: 06/2007
- After 06/2007: pulse rate measured and recorded but no deferral applied
- During the historical period of temporary deferrals: if the initial pulse rate measurement was out of specification, a final assessment was done after a resting period of 15 minutes. (This second measurement did not happen in the more recent period of no deferral)
- Exclusion of period between 06/2006 and 07/2007, to minimize the number of donors who would cross over the two cohorts

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# Follow-up after the abnormal pulse rate measurement:

Identification of study participants in the provincial health insurance database (FIPA)**: 16,647 / 17,333 (96.6%)**

- **Hospitalisations** (MED-ÉCHO, Régie de l'assurance-maladie du Québec)
  - ✓Diagnoses related to acute cardiac ischemia
  - ✓According to ICD-9/ICD-10 classification

- **Deaths** (Institut de la statistique du Québec)
  - ✓Deaths related to cardiac ischemia
  - ✓According to ICD-9/ICD-10 classification

**One year of follow-up** after the abnormal pulse measurement

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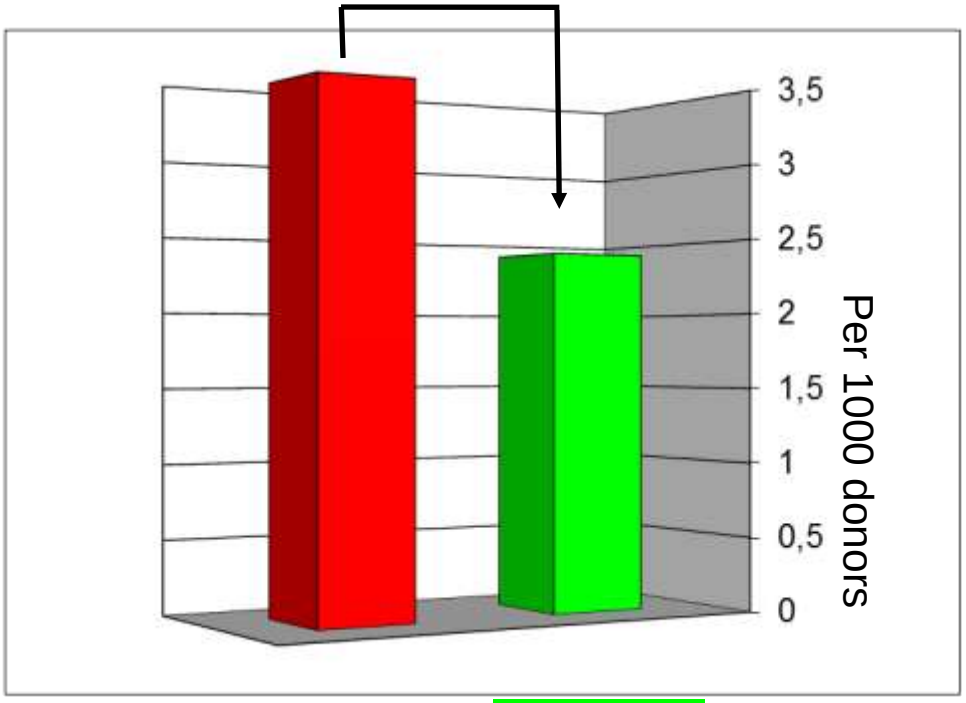
# Unadjusted relative risk of hospitalisation/death within one year after an abnormal pulse rate measurement

**Rate Ratio: 1.4**
(95% CI: 0.8 – 2.5; p = 0.23)




| Temporarily deferred | Allowed to donate |
|---|---|
| 3.5/1000 (21 / 6,076) | 2.4/1000 (26 / 10,671) |

**Note:** Only four deaths identified within one year of follow-up (two in each group of deferred and non-deferred donors)

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# Multivariate logistic regression analysis of the association between deferral practise and the odds of hospitalisation/death for cardiac ischemia among donors with an abnormal pulse rate

| Variable | Odds ratio | 95% Confidence Interval | p-value |
|---|---|---|---|
| **Temporarily deferred vs. Allowed to donate** | 1.7 | 0.9 – 3.0 | 0.08 |
| **Sex (males versus females)** | 2.1 | 1.0 – 4.5 | 0.045 |
| **Age (continuous variable)** | 1.09 | 1.06– 1.12 | <0.001 |
| **No. of previous donations (continuous variable)** | 1.002 | 0.997 – 1.007 | 0.47 |

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# Discussion

- Strengths of the study:
  - Reliance on administrative databases
  - Almost all donors were traced in the health insurance registry
  - Public health care system which ensures that the vast majority of significant adverse events are captured
  - Low mobility of dominantly French-speaking population, which greatly reduces the losses to follow-up
  - Avoidance of recall bias between the two study periods (as opposed to asking donors or their families)

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# Discussion

- Weaknesses of the study:
  - Lack of information on other known risk factors for cardiac ischemia (e.g. smoking)
    - However, risk factors should be quite homogenously distributed between both groups, re: all donors qualified through the same process
  - Historical cohort: possible impact of secular trends in the incidence of ischemic heart disease
  - Slight difference between the two cohorts regarding the manner in which the pulse was evaluated
    - May explain the slightly higher risk of ischemia among donors who were deferred based on a twice abnormal measurement

# Conclusions

- Allowing donations from potential donors with an atypical pulse does not increase their risk of cardiac ischemic events

- Donors who have a high, low or irregular heart rate can safely give blood if they feel well and if they otherwise fulfill the usual qualification criteria

- **There is no value in measuring the pulse rate of prospective blood donors, at least not for the sake of preventing cardiac ischemia**

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Identification of study participants in the provincial health insurance database (FIPA):

- Number of study subjects: **17,333**
- Numbers identified in the provincial health insurance registry: **16,647 (96.6%)**
  - Among donors who were temporarily deferred (historical cohort): **96.8%**
  - Among donors who were allowed to donate (more recent cohort): **98.3%**

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# Demographic characteristics of donors with an abnormal pulse who could be traced within the provincial healthcare databases, compared to those who could not be traced

| | | Tracking in healthcare registry | | | | |
|---|---|---|---|---|---|---|
| | | Successful | | Not successful | | |
| | | N | % | N | % | |
| Gender | F | 7792 | 46.5 | 325 | 55.5 | p < 0.001) |
| | M | 8955 | 53.5 | 261 | 44.5 | |
| Age group (years) | 18 – 29 | 5238 | 31.3 | 199 | 34.0 | |
| | 30 - 39 | 2144 | 12.8 | 51 | 8.7 | |
| | 40 - 49 | 3678 | 22.0 | 117 | 20.0 | |
| | 50 - 59 | 3669 | 21.9 | 129 | 22.0 | |
| | 60 - 70 | 1954 | 11.7 | 85 | 14.5 | |
| | 71 + | 64 | 0.4 | 5 | 0.9 | |
| | Mean age | 40,72* | ± 15.23† | 40,99* | ± 16.34† | p = 0,70) |
| Residence | Montreal region | 6743 | 40.3 | 289 | 49.3 | p < 0.001) |
| | Quebec region | 3163 | 18.9 | 71 | 12.1 | |
| | Other | 6798 | 40.6 | 179 | 30.6 | |
| | Unknown or out of province | 43 | 0.3 | 47 | 8.0 | |
| Number of previous donations | None | 3171 | 18.9 | 164 | 28.0 | |
| | 1 – 3 | 3889 | 23.2 | 128 | 21.8 | |
| | 4 – 6 | 2133 | 12.7 | 54 | 9.2 | |
| | 7 + | 7554 | 45.1 | 240 | 41.0 | |
| | Mean number of donations | 12.75* | ± 28.03† | 12,22* | ± 33.77† | p = 0,71) |
| **Total** | | **16747** | **100** | **586** | **100** | |

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# Hospitalisations/deaths attributable to cardiac ischemia within one year of follow-up

| | | Temporarily deferred 11/2002 – 06/2006 | | | Allowed to donate 06/2007 – 03/2008 | | | All donors | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Total | Hospitalisations or deaths | | Total | Hospitalisations or deaths | | Total | Hospitalisations or deaths | |
| | | N | n | Rate* | N | n | Rate* | N | n | Rate* |
| **Sex** | **F** | 2,981 | 4 | 1.3 | 4,811 | 5 | 1.0 | 7,792 | 9 | 1.2 |
| | **M** | 3,095 | 17 | 5.5 | 5,860 | 21 | 3.6 | 8,955 | 38 | 4.2 |
| **Age** | **18-29** | 2,071 | 0 | 0.0 | 3,167 | 0 | 0.0 | 5,238 | 0 | 0.0 |
| | **30-39** | 859 | 2 | 2.3 | 1,285 | 1 | 0.8 | 2,144 | 3 | 1.4 |
| | **40-49** | 1,287 | 4 | 3.1 | 2,391 | 4 | 1.7 | 3,678 | 8 | 2.2 |
| | **50-59** | 1,217 | 6 | 4.9 | 2,452 | 12 | 4.9 | 3,669 | 18 | 4.9 |
| | **60+** | 642 | 9 | 14.0 | 1,376 | 9 | 6.5 | 2,018 | 18 | 9.2 |
| **Region** | **Montreal** | 2,838 | 10 | 3.5 | 3,911 | 8 | 2.0 | 6,749 | 18 | 2.7 |
| | **Quebec** | 773 | 0 | 0.0 | 2,387 | 8 | 3.4 | 3,160 | 8 | 2.5 |
| | **Other** | 2,465 | 11 | 4.5 | 4,373 | 10 | 2.3 | 6,838 | 21 | 3.1 |
| **Previous donations** | **None** | 1,456 | 2 | 1.4 | 1,715 | 1 | 0.6 | 3,171 | 3 | 0.9 |
| | **1-3** | 1,532 | 3 | 2.0 | 2,357 | 5 | 2.1 | 3,889 | 8 | 2.1 |
| | **4-6** | 799 | 1 | 1.3 | 1,334 | 5 | 3.7 | 2,133 | 6 | 2.8 |
| | **7+** | 2,289 | 15 | 6.6 | 5,265 | 15 | 2.8 | 7,554 | 30 | 4.0 |
| **TOTAL** | | **6,076** | **21** | **3.5** | **10,671** | **26** | **2.4** | **16,747** | **47** | **2.8** |

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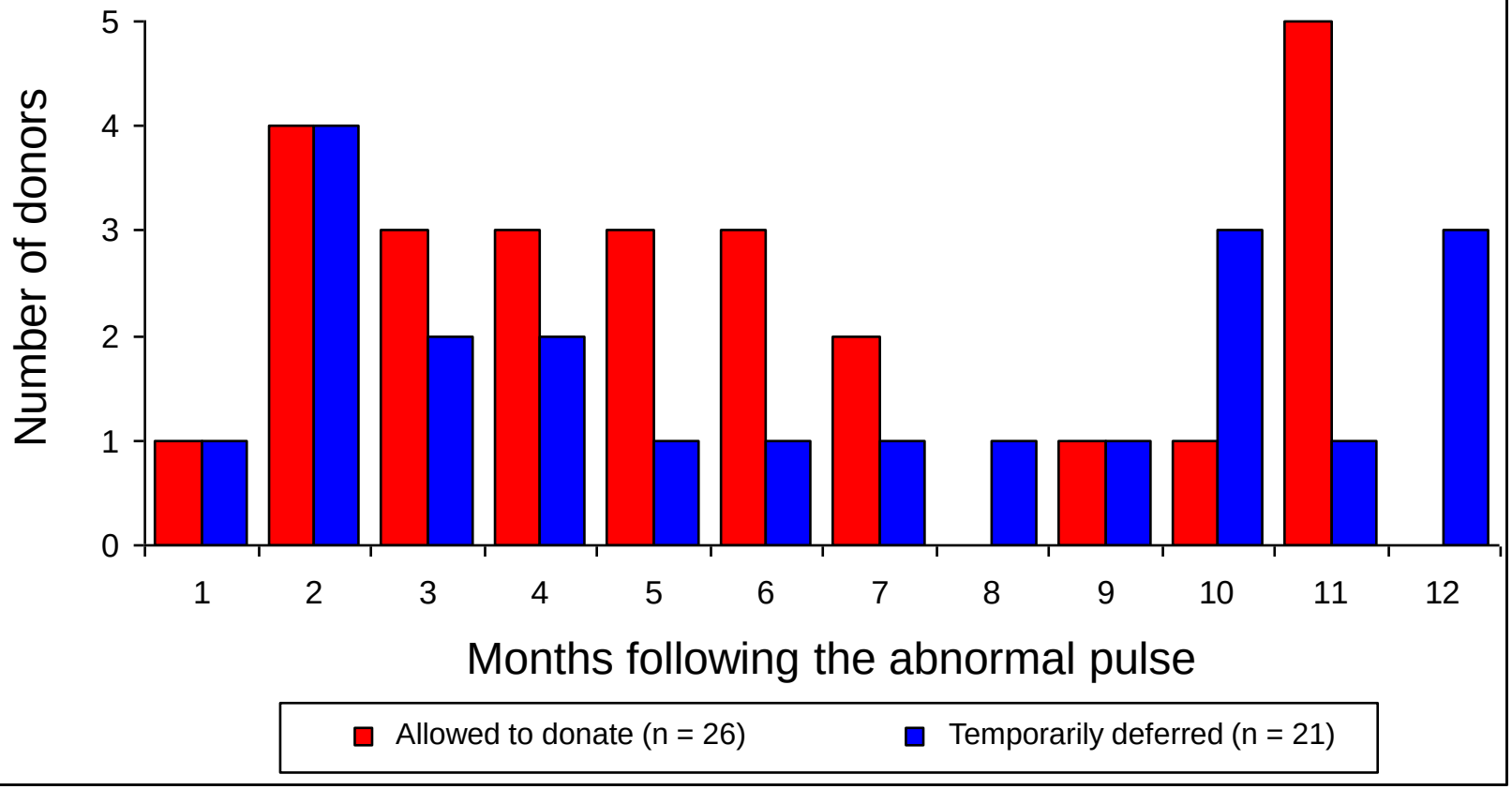
# Chronology of hospitalisations/deaths following the abnormal pulse measurement




**Note:** No clustering of events in the early months among donors who were allowed to donate ($X^2 = 1.08$, $p = 0.58$)

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