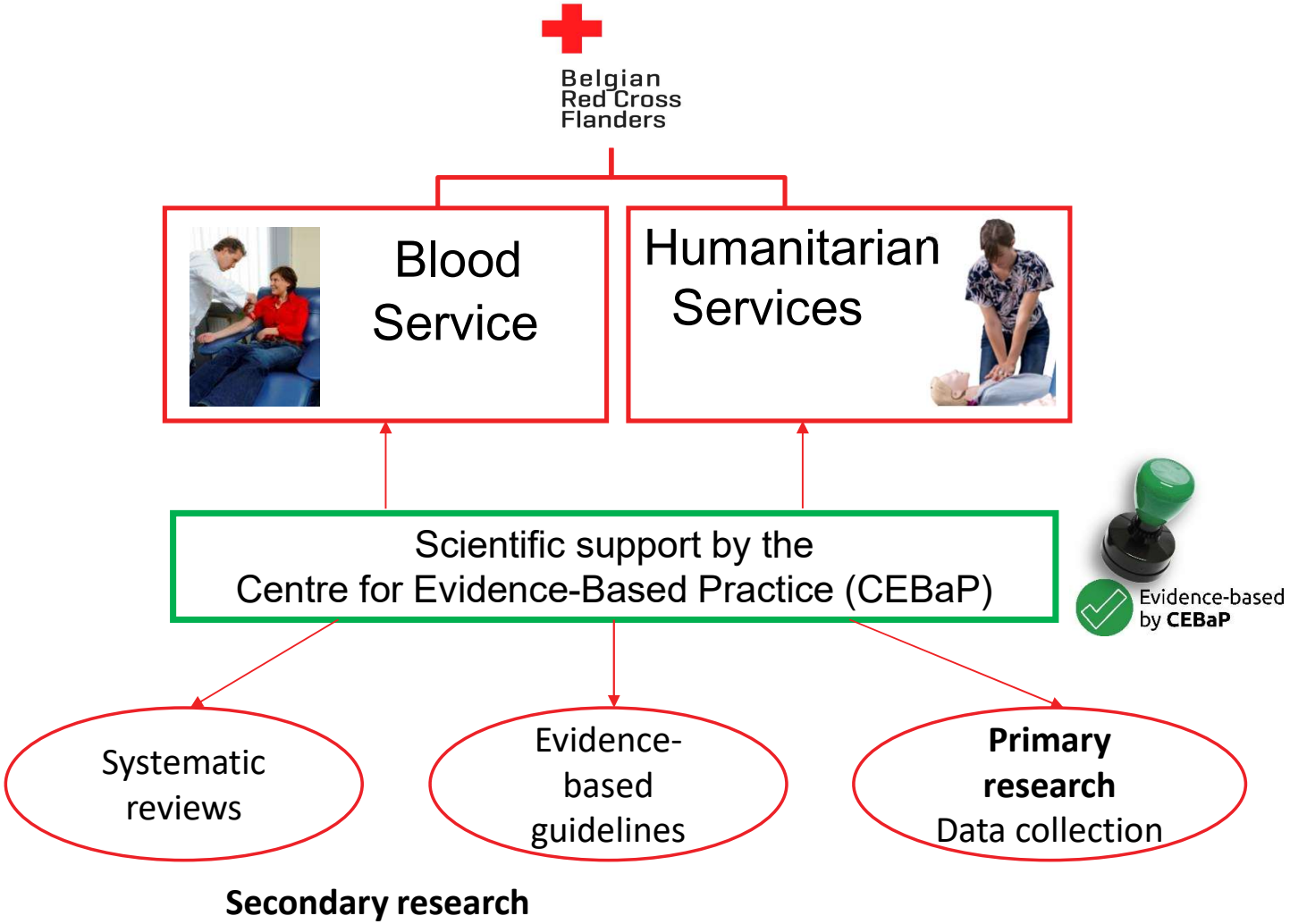
Rode Kruis Vlaanderen

Blood donation deferral for men who have sex with men

Luce Mosselmans – PhD candidate - Junior Researcher CEBaP

16 May 2024 – AVVT-BVBW symposium

Mission Centre for Evidence-Based Practice (CEBaP)



Centre for Evidence-Based Practice (CEBaP)

Emmy De Buck, Director
Hans Van Remoortel, Coordinating Researcher
Jorien Laermans, Researcher

Hans Scheers, Researcher
Tine D'aes, Researcher
Irvin Kendall, Researcher, PhD student

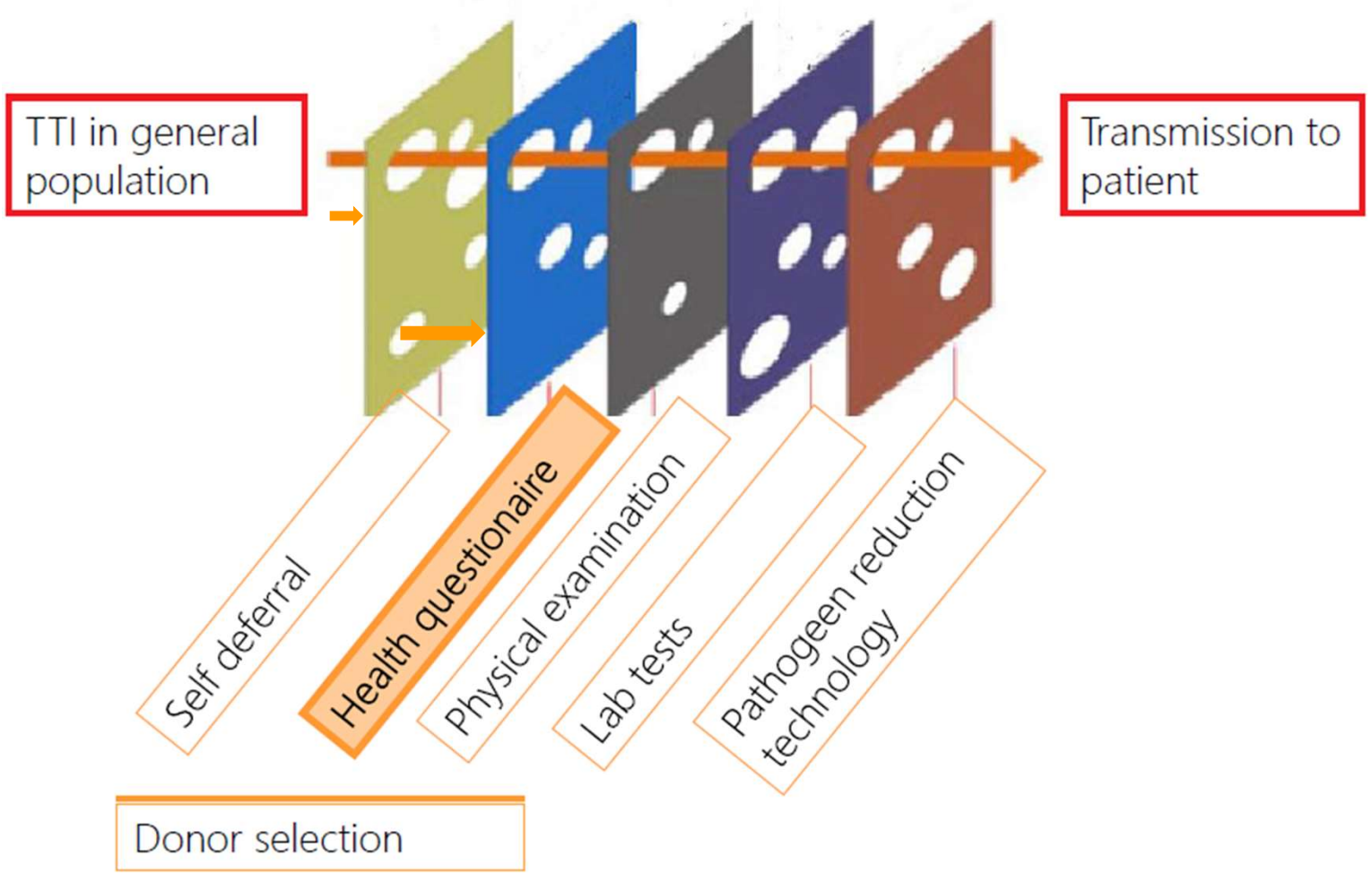
Pieter Severijns, Researcher
Luce Mosselmans, Junior Researcher, PhD student
Open position - Researcher

Blood donor deferral for men who have sex with men

- Blood banking safety
- MSM deferral in Western countries and in Belgium
- Future research at BRC-F

Rode Kruis Vlaanderen

Safety in blood banking



Evolution of blood safety

1980s:

HIV/AIDS outbreak

Donor selection: MSM and IDU banned

Serological test from 1986

1990s:

Introduction of NAT tests in blood banking

2000s-2010s:

Introduction of pathogen inactivation technology for plasma and platelets

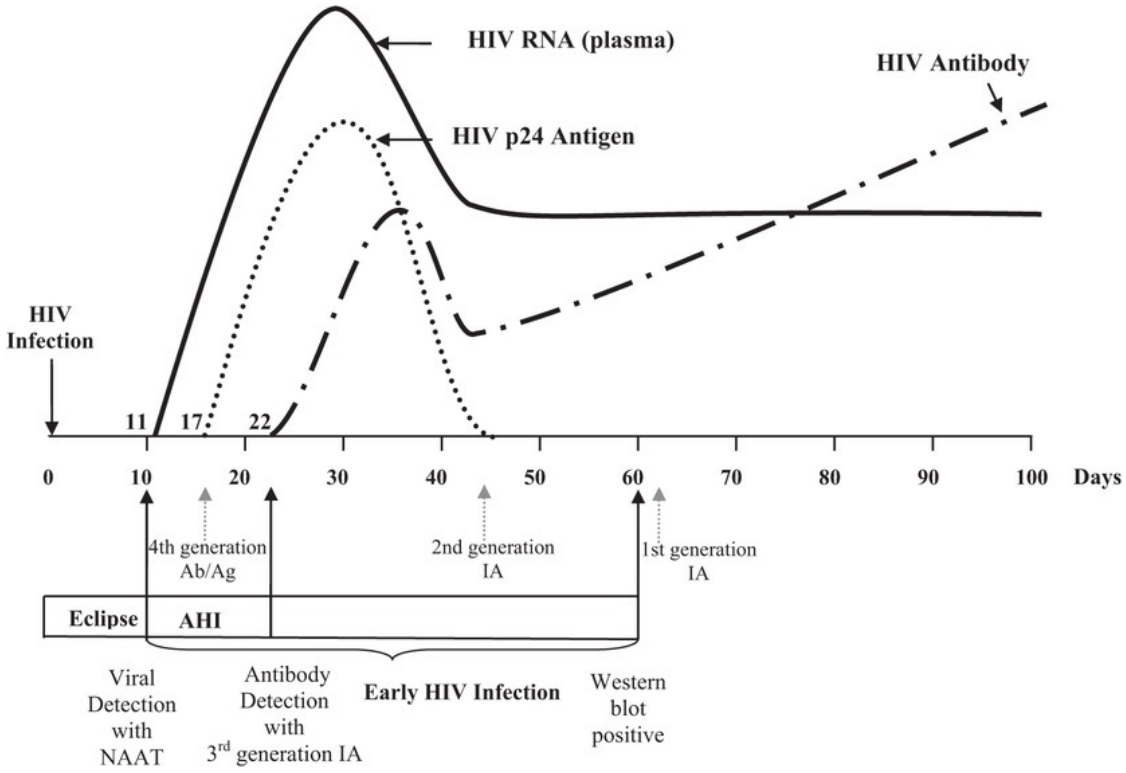
(near) future:

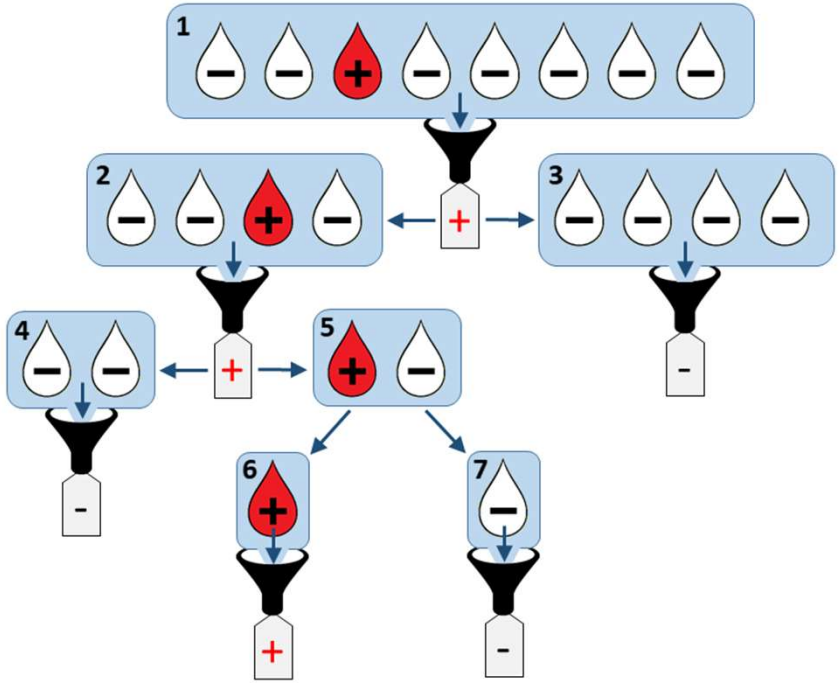
Pathogen inactivation for whole blood?

- Increasing blood safety
- Improved technology (assays and PRT)
- Changing epidemiology of HIV

→ **Is MSM deferral still needed/justified?**

Remaining risks: window period infections and emerging pathogens





Minipooling of samples

Balancing rights, risks and costs

Right to **safe blood products** for patients

Precautionary principle

Benefits of donor deferral, lab assays, pathogen inactivation technology

Vs right to **non-discrimination** based on gender and sexual identity

Vs **risk-based** decision making

Costs of donor deferral, lab assays, pathogen inactivation

Deferral of men who have sex with men from blood donation

- **Permanent ban:** every man who has ever had sex with another man since 1977 is permanently deferred from blood donations

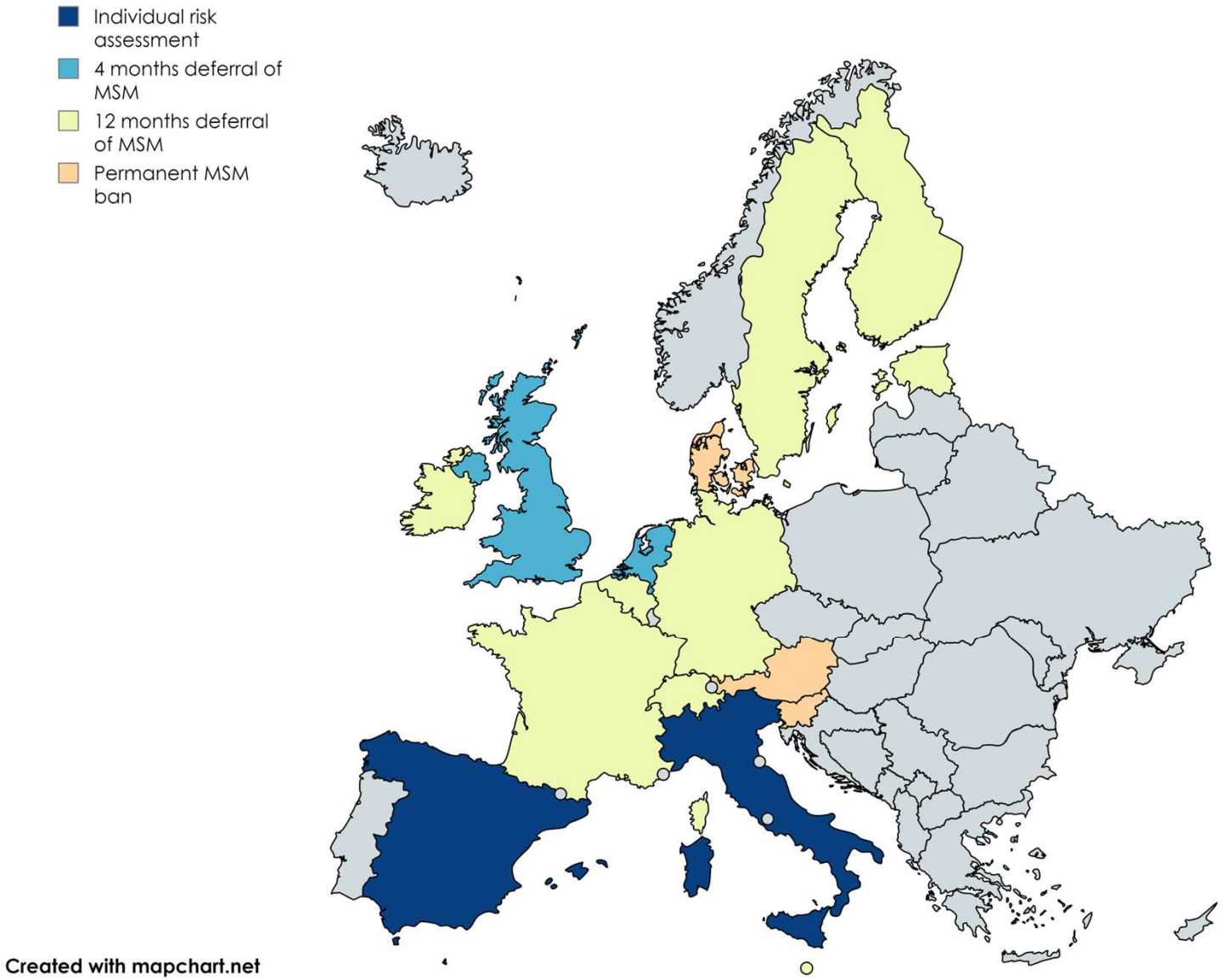
- **Temporary deferral:** after a deferral time since last sexual contact with another man, blood donations are accepted

  Temporary deferrals ranging from 3months to 5years

- **Individual risk assessment:** all blood donors are assessed for eligibility based on individual risk profile (unprotected (anal) sex, new sexual partner, multiple sexual partners)

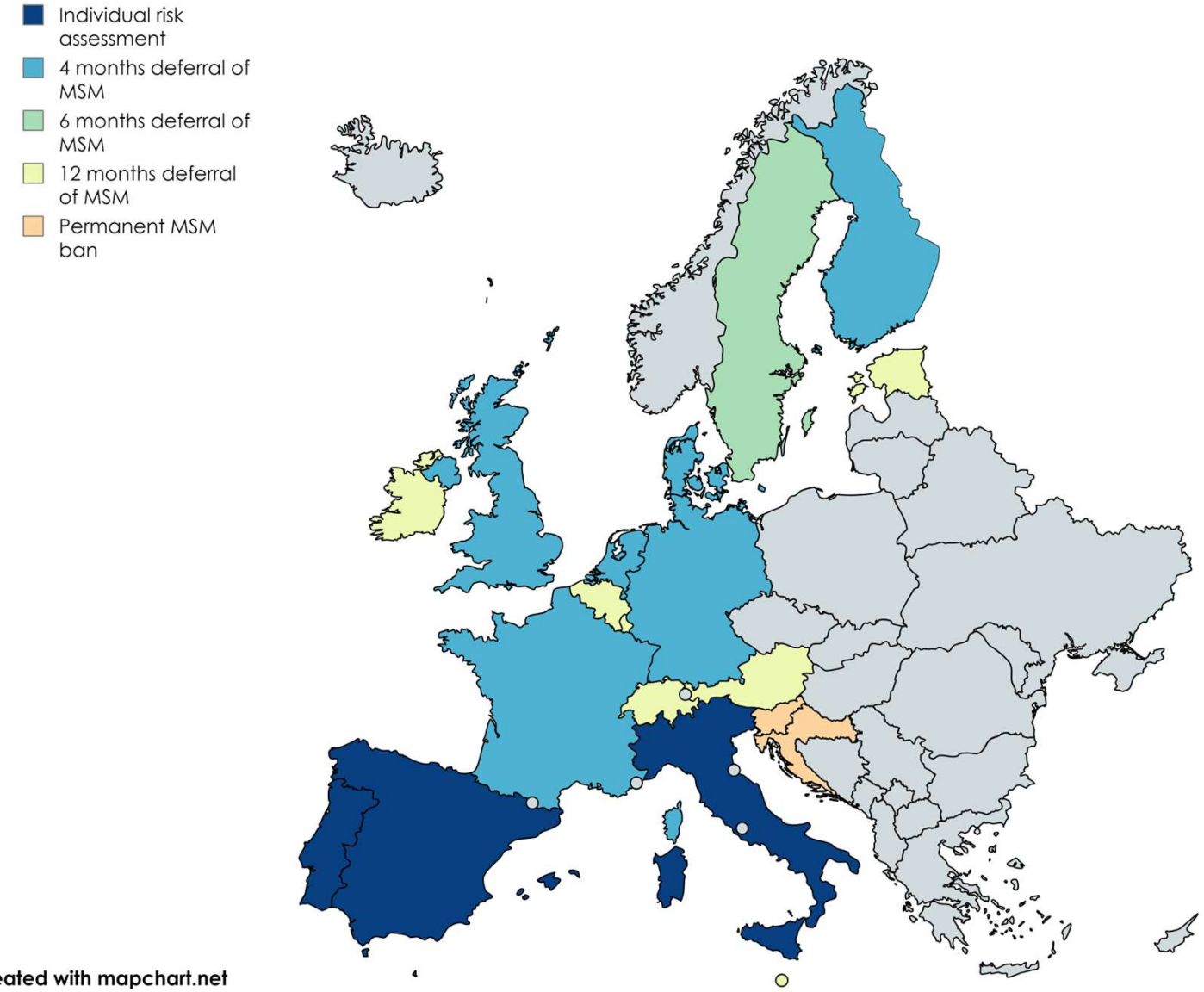
- **Plasma quarantine programmes:** (USA/Israel): plasma donation is frozen and kept in quarantine until a next donation is received, if 2nd donation also tests –ve to all TTIs, plasma is released for use.

2019



Data from European Blood Alliance: https://europeanbloodalliance.eu/resources/msm-policy-and-prep-pep/

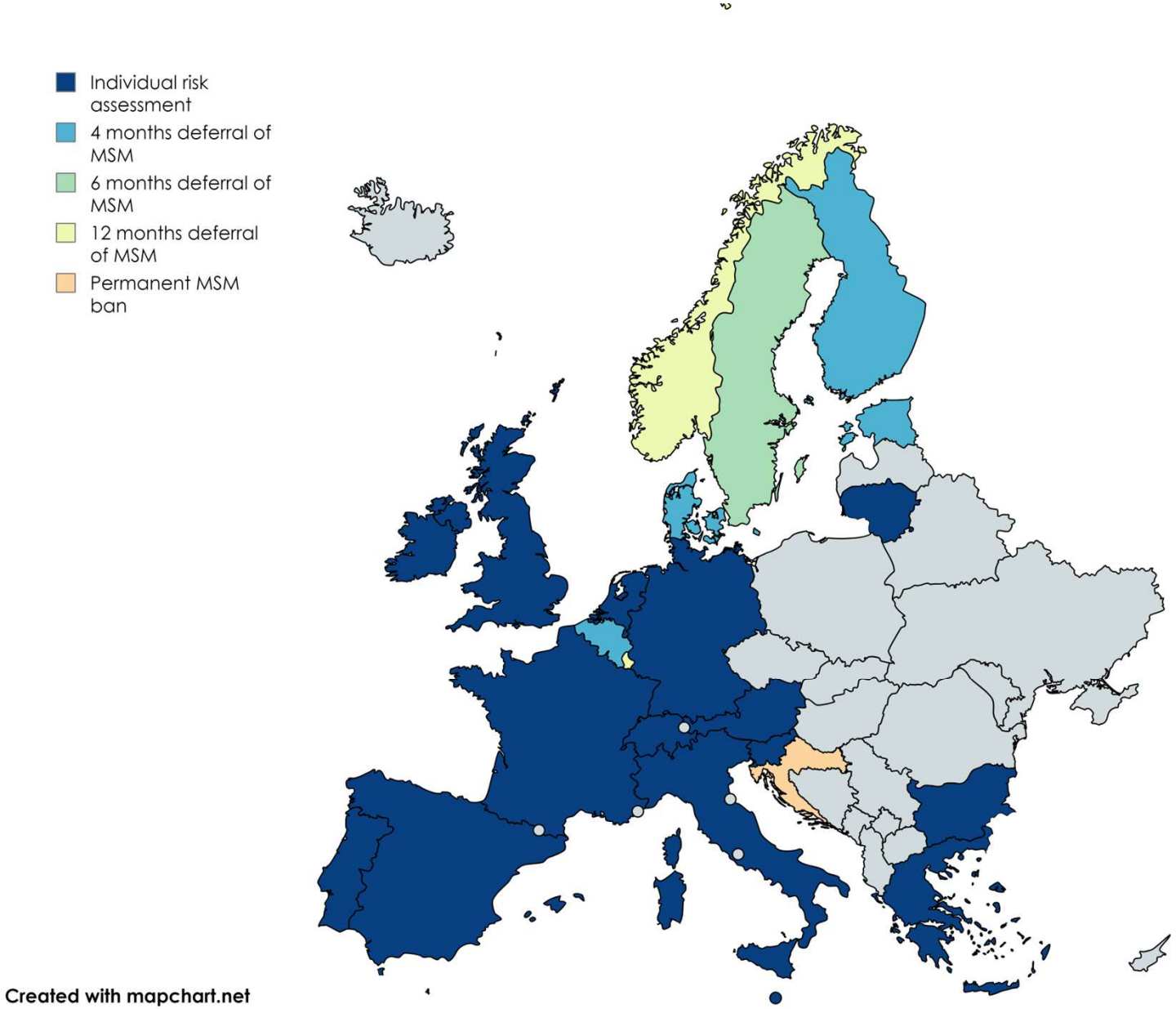
2021



Created with mapchart.net

Data from European Blood Alliance: https://europeanbloodalliance.eu/resources/msm-policy-and-prep-pep/

2023



Data from European Blood Alliance: https://europeanbloodalliance.eu/resources/msm-policy-and-prep-pep/

What is the impact of easing MSM deferrals on blood safety in Western countries?

- Observed data:
  - Very limited evidence:
    - Observational studies often uncontrolled for counfounding factors
    - Very low observed cases (TTIs are extremely rare)

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REVIEW

Vox Sanguinis ISBT International Society of Blood Transfusion

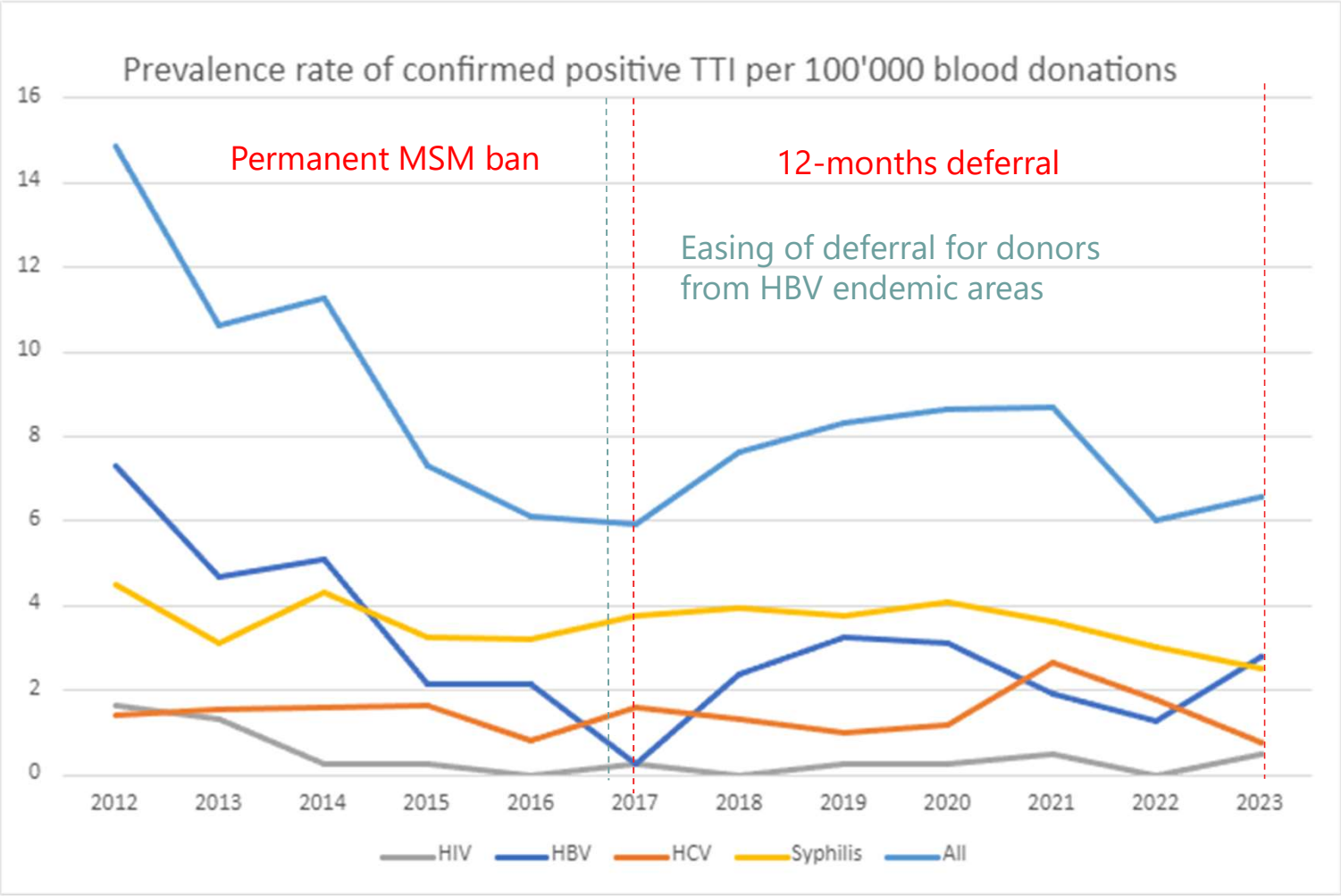
Men who have sex with men and risk for transfusion-transmissible infections in blood donors in Western countries: A systematic review update

Natalie Schroyens[1,2] | Vere Borra[1,2] | Veerle Compernolle[3,4] | Philippe Vandekerckhove[2,5,6] | Emmy De Buck[1,2]

- Modelled data:
  - Estimations of risk based on simulations / mathematical models
  - Conducted by blood establishments prior to implementing IRA: Canada, UK, USA, France
  - Systematic review ongoing

(Prospero ID:524737)
https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=524737

What about observed prevalence of TTIs in blood donors in Flanders?



Increase in TTIs/HBV after 2017 due to MSM or due to foreign-born donors?

What is the trend after change to 4-months deferral (1st July 2023)?

Observational study TTIs in Belgian blood donors: study planned 2025-2026

- **Trends analysis** of prevalence of TTIs on national data 2012-2025

- **Case control study:**
  - What are risk factors for TTI+
    - MSM
    - Other sexual risk behaviours
    - Foreign-born donors
  - Has MSM become a more important risk factor for TTIs as policy has eased
  - If there is an increase in TTIs, is this attributable to MSM or other risk factors?

Is individual risk assessment feasible in Belgium ?

- Risk factors for TTIs in MSM:
  - Multiple/ new sexual partners
  - Chemsex
  - Unprotected anal sex
  - PrEP use
  - History of STIs such as chlamydia and gonorrhea

- IRA donor questionnaires from other countries:
  - Anal sex with a new or with multiple partners
  - PrEP use

Can we maintain/improve blood safety while changing donor screening?

Are these questions sensitive and specific enough to detect high-risk donors?

Are these questions understood and accepted by blood donors?

Donor questionnaire sensitivity and specificity

		Genomic testing		
		TTI positive	TTI negative	
IRA donor questionnaire	Positive for risk factor(s) Ineligible to blood donation	True positive (TP)	False positive (FP)	**Positive predictive value** = TP/ (TP+FP)
	Negative for risk factor(s) Eligible to blood donation	False negative (FN)	True negative (TN)	
		Sensitivity = TP /(TP+FN)	**Specificity** = TN / (FP+TN)	

TTI- turned down for donation: potential threat to blood supply

TTI+ allowed to donate blood: potential threat to blood safety

Aim: identify (combination of) items for donor questionnaire with:

- Sensitivity: very high
- Specificity: as high as possible

Assessment of IRA feasibility in Belgium: study planned in 2025-2026

Q1: IRA

- Measure of **sensitivity**:
  - > In recently diagnosed HIV/syphilis patients:
  - > How many infected individuals are correctly detected by the medical donor questionnaire
  - > Comparison between current donor questionnaire and IRA questionnaire
- Measure of **donor loss** (~specificity)
  - > In current blood donors
  - > Calculate deferral rates for an IRA questionnaire among those who are currently accepted

Q2: survey

- Measure of **donor comfort**
  - > In current blood donors and potential future blood donors
  - > Survey on the donor questionnaire: are questions clear, accepted, too sensitive? Do we risk losing a subgroup of donors due to uncomfortable questionnaires?

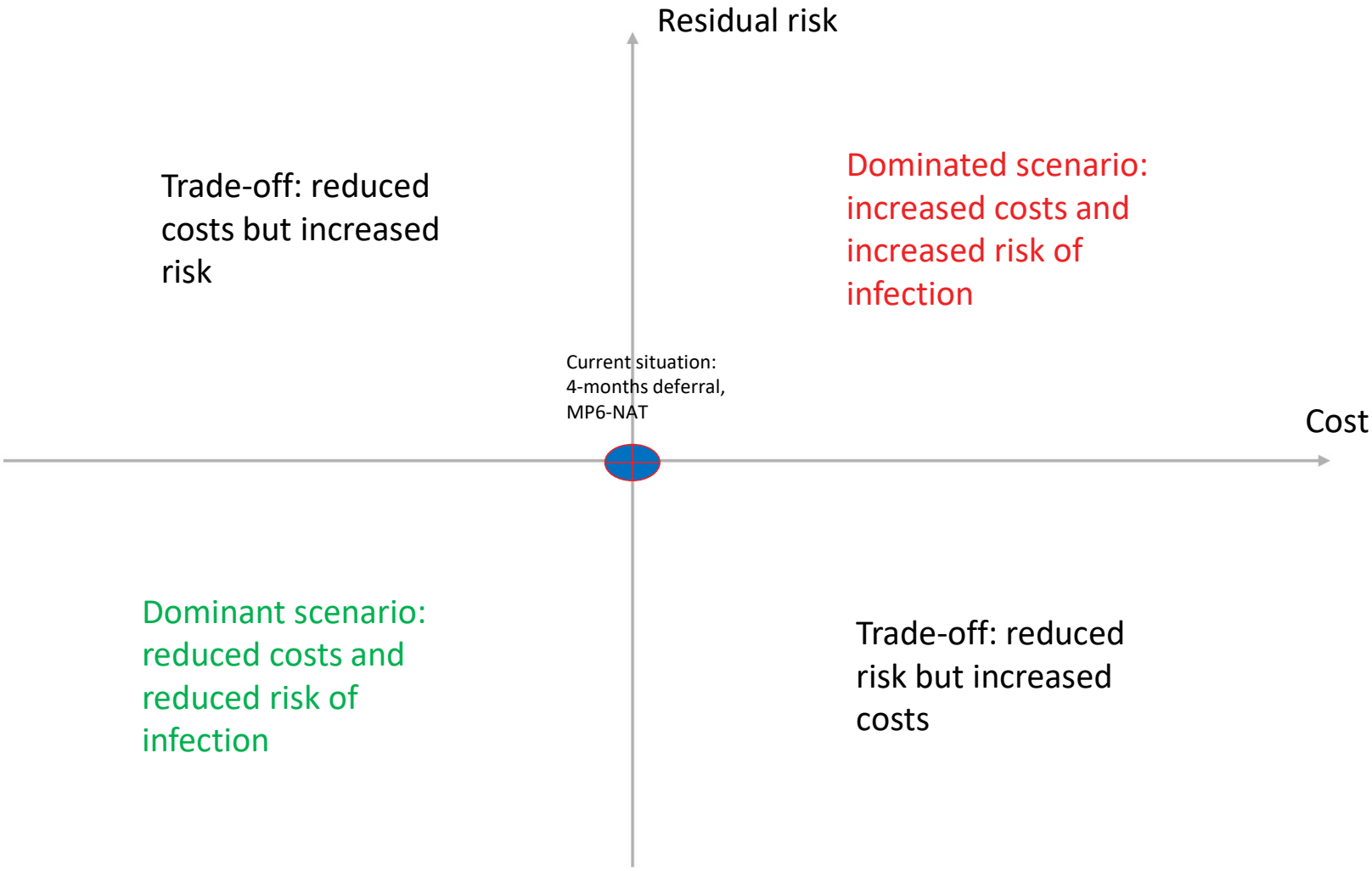
What are the implications of evolving blood donor policies on the cost of blood products?

- Change testing strategy in March 2024: MSM blood donors are tested individually for TTIs.
  - → increase in sensitivity
  - → increase in costs

  - **Precaution** principle: in absence of knowledge of increased risk of TTI due to MSM policy change, individual testing of blood samples

- **Health economic analysis** (study planned 2027)
  - What would be the residual risk for TTI in Belgium under IRA?
  - If IRA is to be implemented, can we still safely use minipools of 6?
  - What is the cost-effectiveness of minipools under different deferral scenarios?

Scenario		Measure	
MSM deferral policy	**Lab test**	**Residual risk**	**Cost**
4-months deferral	ID-NAT	Estimation of blood donors presenting to blood donations during infectious window period and prevalent TTI risk WP calculated for each testing option based on sensitivity of test	Cost of donor recruitment Cost of collecting blood: - Donor opportunity time - Staff time - Equipment Cost of blood processing Cost of laboratory testing, including costs of confirmatory test when screening is positive: - Tests and reagens - Staff time - Investments/equipments (number of PCR /lab space)
	6MP-NAT		
	6MP-NAT / ID-NAT if MSM		
IRA/ no MSM deferral	ID-NAT	Estimation of additional MSM blood donations + incidence and prevalence of TTI on MSM blood donors = increase in blood donations during infectious window period	
	6MP-NAT		
	6MP-NAT / ID-NAT if MSM		


Residual risk
Trade-off: reduced costs but increased risk
Dominated scenario: increased costs and increased risk of infection
Current situation: 4-months deferral, MP6-NAT
Cost
Dominant scenario: reduced costs and reduced risk of infection
Trade-off: reduced risk but increased costs

Establishing an evidence ecosystem for blood donation by men who have sex with men

PhD project: 2024-2028

Study 1: SR: what is the **modelled** impact of changing MSM donor deferral policy on blood safety in Western countries? (2024)

Study 2: **observational study BRC**: prevalence/incidence/residual risk of TTIs during permanent ban, 12-months and 3-months MSM deferral policies (2025-2026)

Study 3: Is **individual risk assessment** of MSM blood donors feasible in Belgium? (2026)

Study 4: Health-economic analysis: what are the implications of evolving blood donor policies on **the cost** of blood products? (2027)

Stakeholder engagement: formal stakeholder analysis en communication plan to be implemented throughout the PhD project.

Questions? Want to keep updated with the research?

www.cebap.org

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Thank you for your attention

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