



# PARIS

**FAST-TRACK CITIES 2024**

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## The potential health economic value of universal opt-out HIV testing in emergency departments in Italy

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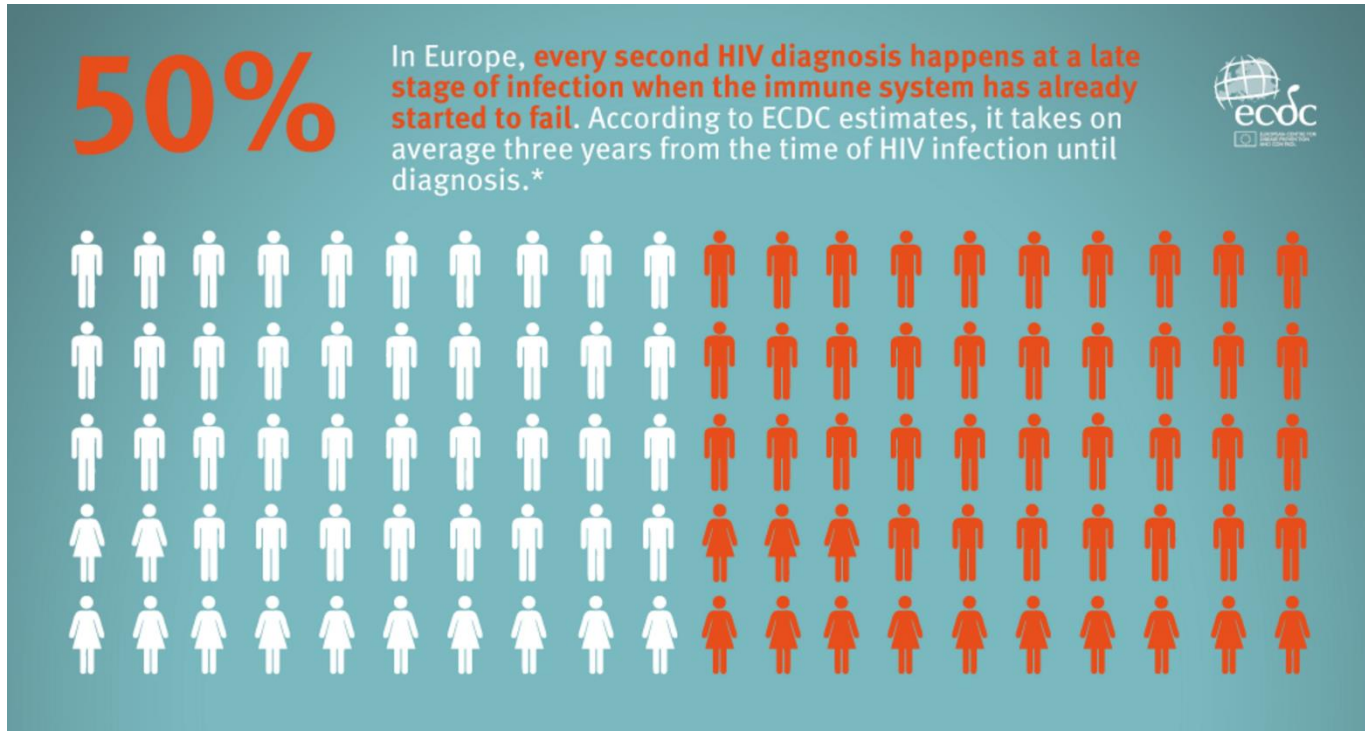
# Disclosure of interests

- Murad Ruf is an employee of Gilead Sciences.
- This study was sponsored by Gilead Sciences.

# Big picture I

## Unmet need Europe

In Europe on average, **1 in 2** new HIV diagnoses are made at a **late** stage of infection<sup>1</sup>.



- Late diagnosis (CD<350)
- Timely diagnosis

<sup>1</sup>ECDC, 2020.

**Mortality:** 7-fold increased risk of death in the first year after diagnosis

Public Health England 2021

**Economics:** 1<sup>st</sup> year and lifetime cost per person with late diagnosis ~**50% higher**

Economic report  
National Institute for Care Excellence (NICE), UK 2016



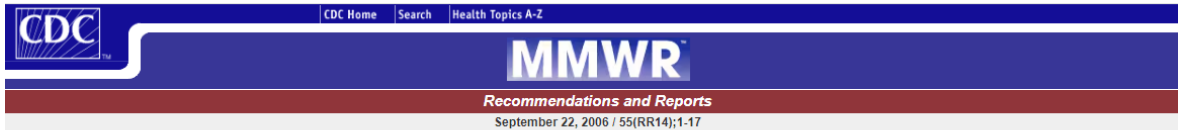
## Big picture II

**CDC 2006**

‘Opt-out testing recommended’

**ECDC 2018**

‘Written consent for HIV, Hep B, Hep C no longer necessary’



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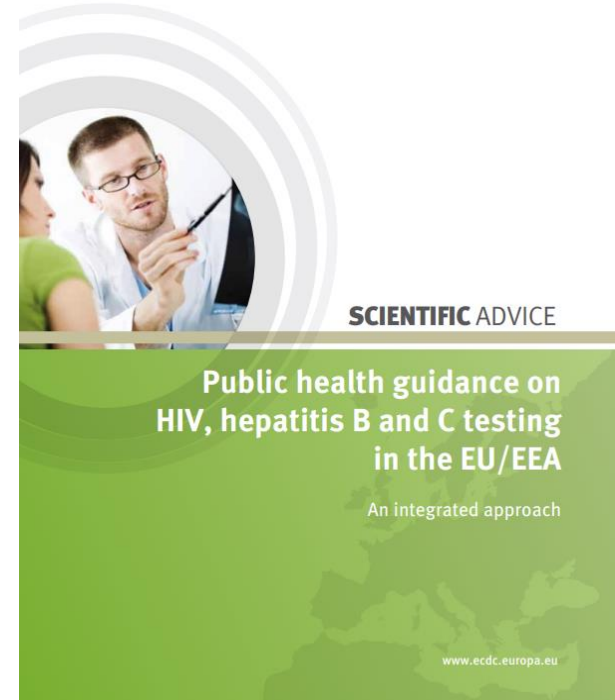
### Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings

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# Background Italy

## HIV landscape in Italy

- HIV diagnoses have been falling (Figure 1).

### However:

- Estimated 13,000-15,000 people with **undiagnosed** HIV.
- ~ **60%** persistently **late** HIV diagnoses in Italy.
- **Particularly**, many late diagnoses are in **heterosexuals** aged >40<sup>2</sup>.

## HIV testing in Italy

- Currently 'Opt-in' testing. Requires **signed** consent (Law 135/1990).
- Offered **primarily** at sexual health and drug use support centres<sup>2-6</sup>.
- In hospitals and emergency departments (EDs), predominantly HIV **indicator** condition testing<sup>4-7</sup>.
- **Innovative strategies** are required to meet UNAIDS HIV targets<sup>2,8</sup>.

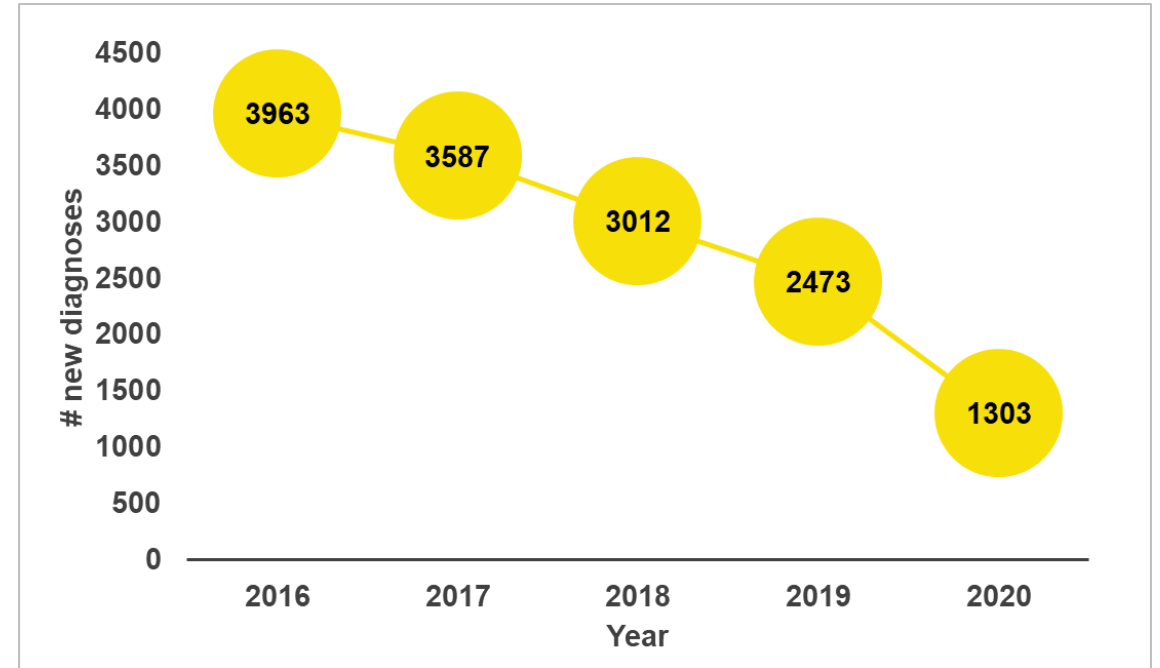


Figure 1. Number of new HIV diagnoses in Italy, 2016-2020<sup>2</sup>.

<sup>2</sup>L'Istituto Superiore di Sanità, 2022; <sup>3</sup>WHO, 2021; <sup>4</sup>Galli et al. Infez Med, 2020; <sup>5</sup>Ministero della Salute, 2011; <sup>6</sup>PNAIDS, 2016; <sup>7</sup>Barbanotti et al., 2023; <sup>8</sup>UNAIDS, 2024.

# Background ED testing

## Universal opt-out\* HIV testing in Emergency Departments

*\*Testing is offered to all patients undergoing routine bloods with the **option** to decline<sup>9</sup>.*

A. EDs are a key touch point for people who **engage less** with routine health services<sup>10</sup>.

B. **European** studies show the clinical effectiveness of universal opt-out ED testing in high prevalence areas<sup>13–16</sup>.

C. ED HIV testing is cost-effective in the **US**<sup>11</sup>.  
Routine testing has been recommended in Europe since 2010<sup>12</sup>.

D. **Opt-out** testing results in higher **uptake** than opt-in<sup>10</sup>.



**Study aim:** to estimate the health-economic value of universal opt-out ED testing in Italy - “*what-if*”?

**Purpose:** to inform regional and national **dialogue**

<sup>9</sup>CDC, 2023; <sup>10</sup>Simmons et al. HIV Med 2022; <sup>11</sup>Mwachofi et al. AIDS Care 2021; <sup>12</sup>ECDC, 2017; <sup>13</sup>Parry et al. Epidemiol Infect 2018; <sup>14</sup>Smout et al. Sci Rep 2022; <sup>15</sup>Vaz-Pinto et al. HIV Med 2022; <sup>16</sup>Hill-Trout et al. BHIVA 2023 Spring Conference.

# Innovative optimised emergency department clinical pathway

UK example

## A. Local ED testing policy: Opt-out consent

*“Any patient who has a blood test in this department also has an HIV test – is that ok?”*



## B. Testing: Electronic systems

Order Set Summary					
Order Set:	AE				
Order Items					
Order	Sequence	Seq No	Start Date	Start Time	Stop Date
<input checked="" type="checkbox"/> HIV antigen/antibody					Routine
Requestor's responsibility to obtain Patient's consent.					
<input checked="" type="checkbox"/> FBC & Diff					Routine
The need for Blood Film will be determined by the lab staff on the basis of the FBC and clinical condition of the patient. In special circumstances please contact the lab.					
<input checked="" type="checkbox"/> Renal Profile (Chemical Pathology)					Routine
Includes Na, K, Creatinine & eGFR. Urea is NOT INCLUDED: Indications for separate ordering of urea: pre-renal failure, hyper-catabolism, gastrointestinal bleed, monitoring of dialysis.					

## C. Enhanced linkage to care

- “**No** news is good news”
- Follow-up directly by clinical HIV teams through **dedicated care coordinators**
- **No** extra work for ED staff

# Methods

Theoretical model: a hybrid decision-tree Markov model

## Intervention

An **opt-out** HIV test is **triggered** by the electronic patient record (**EPR**) system for all adults presenting to ED requiring **routine** blood tests.



## 'Standard of care' comparator in Italy

**Indicator** testing for patients presenting with opportunistic infections.

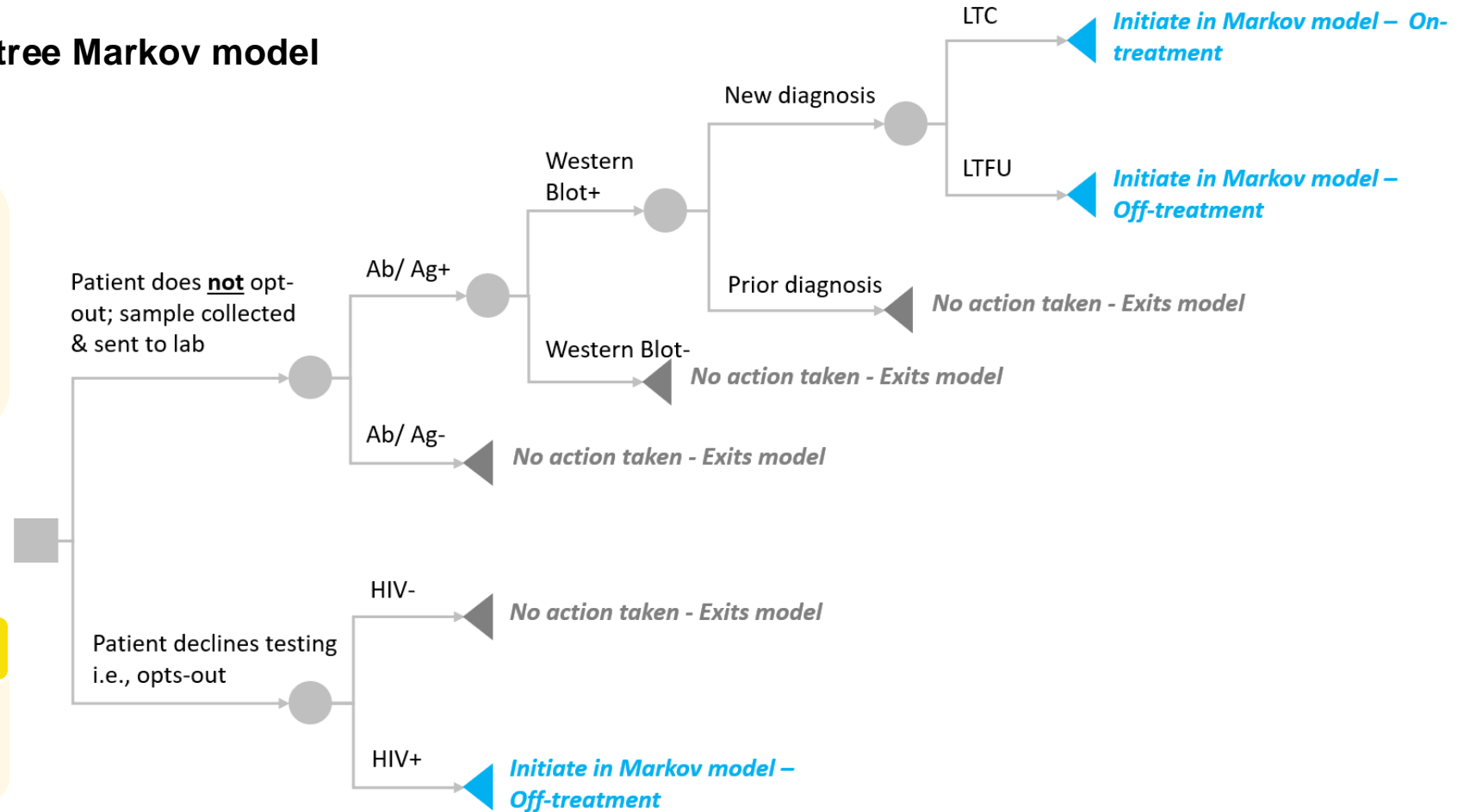


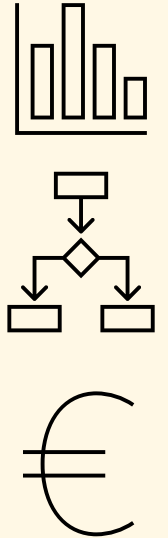
Figure 2. Universal opt-out ED testing algorithm decision tree



## Methods

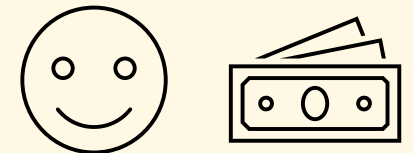
### Model inputs

- No real-world evidence on opt-out HIV testing from Italy. No data on HIV prevalence in Italian EDs. Data from the largest European studies were used.
- Primary analysis:
  - Vaz-Pinto et al.<sup>15</sup> EPR-based intervention in a medium-to-high prevalence setting in Portugal (0.52%). Considered more representative of the target population in Italy
- Costs sourced from published literature, including clinical trials and Italian costing studies and databases.
- Several scenario analyses were conducted.



### Primary outcomes

Life years, quality-adjusted life years (QALYs), and costs.



<sup>15</sup>Vaz-Pinto et al. HIV Med 2022.

# Results – Primary analysis

## Improved diagnosis and linkage to care rates

Universal **opt-out** testing compared to SoC:

- **15.8** additional **new** HIV diagnoses (16.0 vs 0.2)
- **14.5** more people **linked** to care (14.7 vs 0.2)

**per 10,000** people presenting to ED.

## Cost-effectiveness

**ICER:** 24,680 €/QALY for universal opt-out testing vs indicator testing for HIV prevalence (Vaz-Pinto et al.<sup>15</sup>): **0.52%**.

Opt-out testing was **cost-effective** when HIV prevalence was  $\geq 0.25\%$  assuming a **WTP** threshold of 30,000 €/QALY (Figure 3).

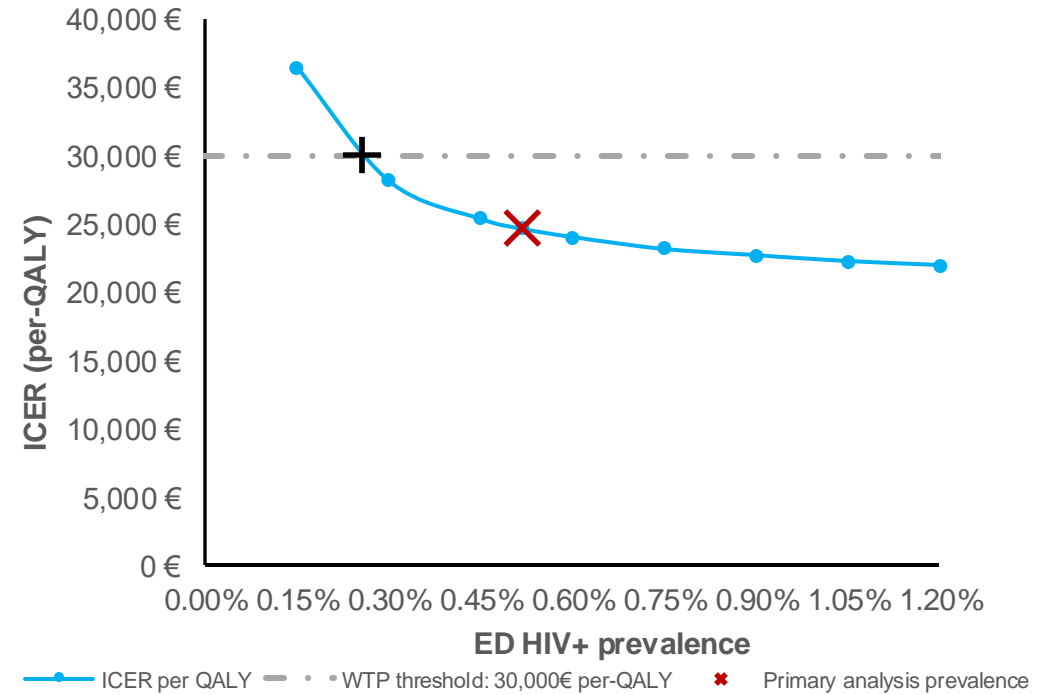


Figure 3. ICER (per-QALY) estimates for different ED HIV prevalence

<sup>15</sup>Vaz-Pinto et al. HIV Med 2022.

**Abbreviations:** ED: emergency department; ICER: incremental cost-effectiveness ratio; WTP: willingness-to-pay; QALY: quality-adjusted life year; SoC: standard of care.

# Strengths & Limitations

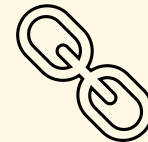
## Strengths

- **First** study to look at the health economic value of opt-out HIV testing in EDs in Italy.
- Estimated ED HIV prevalence cost-effectiveness threshold can **inform** evidence-based discussions regionally and locally on this testing strategy.
- Findings can guide Italian **real-world** data generation.



## Limitations

- **No** real-world data from Italy. Data from other European studies were used.
- People previously diagnosed were **assumed** to be engaged in care  $\neq$  reality.
- The model did **not** look at transmissions averted (U=U).



# Conclusions & Implications



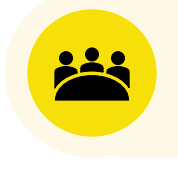
Universal opt-out ED testing in Italy could be a **cost-effective** strategy to **increase** the number of HIV diagnoses.



We may **underestimate** the full benefit as we did not consider prior-disengaged diagnoses or transmissions averted (**U=U**).



Italian **real-world** data is needed to verify our findings.



Stimulate regional & national **dialogue** on HIV testing policies.

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Thank you

