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Wetgevend kader POCT en toepassingen: Inleiding en overzicht

Lieve Van Hoovels
Clinical biologist AZORG

12/10/2026

Erasmus Hoge School, Brussel
Navorming POCT medewerker/coördinator

Overview

1. Introduction

- 1.1 AZORG
- 1.2 Definition of POCT
- 1.3 Current applications of POCT
- 1.4 Proven effectivity
- 1.5 Analytical performance
- 1.6 User friendliness

2. POCT regulations and guidelines

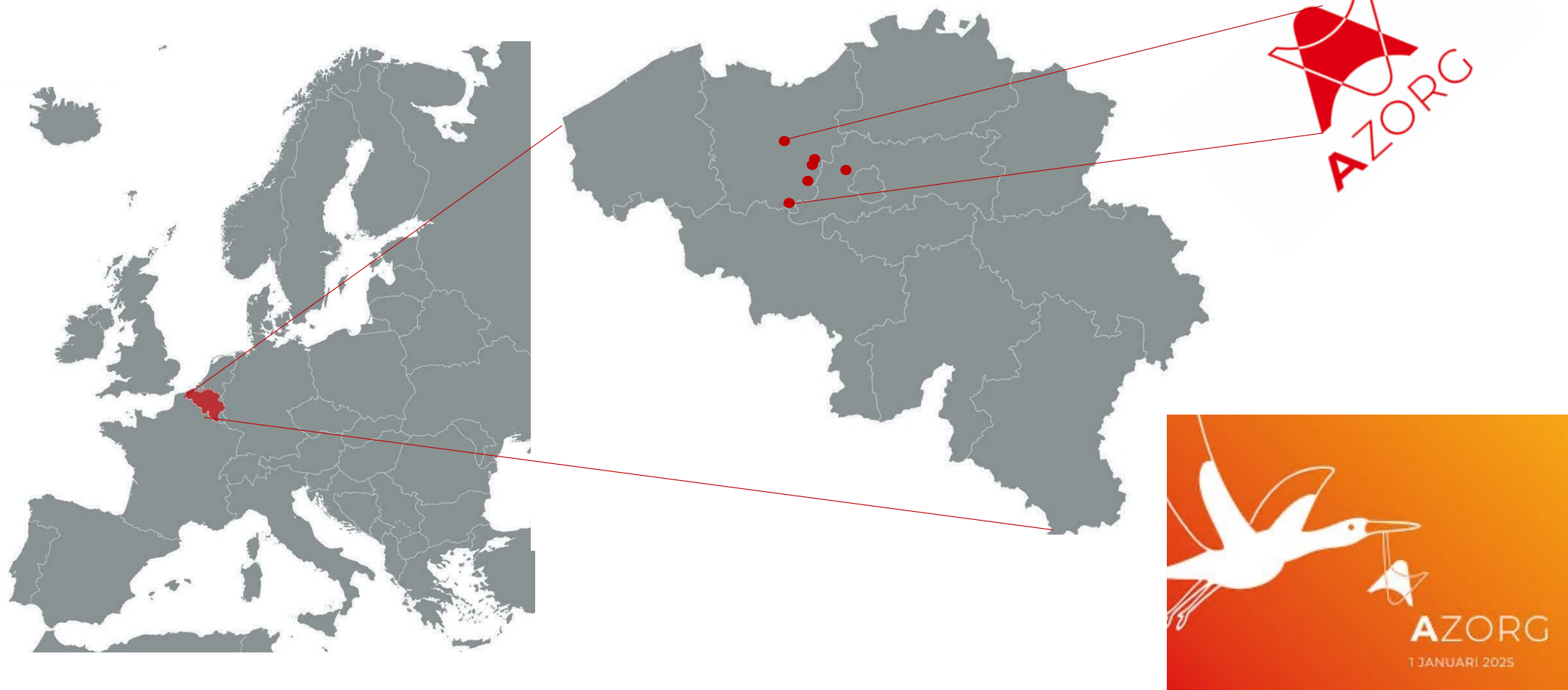
- 2.1 Role of the laboratory in POCT
- 2.2 POCT governance within the laboratory
- 2.3 POCT governance outside the laboratory
- 2.4 Governance aim
- 2.5 Regulation of POCT users
- 2.6 Regulation of POCT in primary care

3. Conclusion



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1.1 AZORG hospital



1.1 AZORG hospital

Hospital admissions

58 000



Emergency visits

90 000



Day Clinic contacts

12 000



Consultations

950 000



Childbirths

2500



Beds

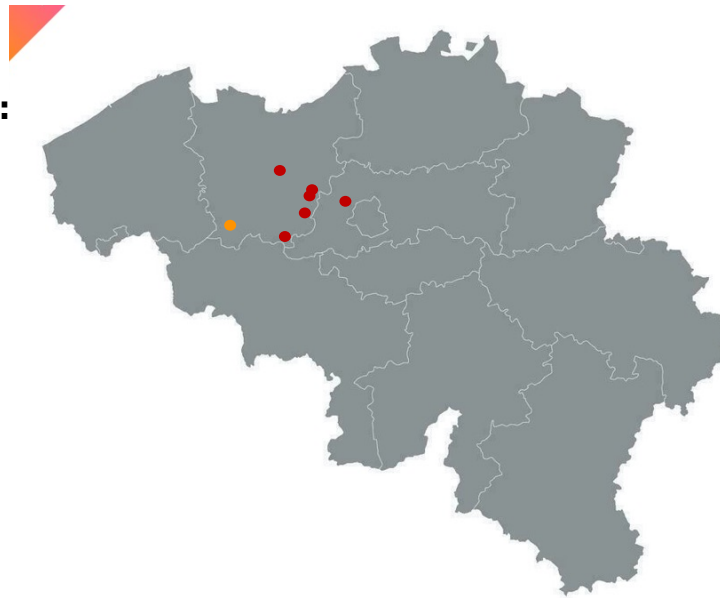
1200



1.1 AZORG hospital

Clinical laboratory

- **Main site:** Merestraat Aalst
- **Satellite labs:**
 - Moorselbaan Aalst
 - Geraardsbergen
 - Asse
 - **AZ Oudenaarde**
- **Blood collection centra:**
 - Wetteren
 - Ninove



Samples

- In-house practitioners
- General practitioners
- Other labs

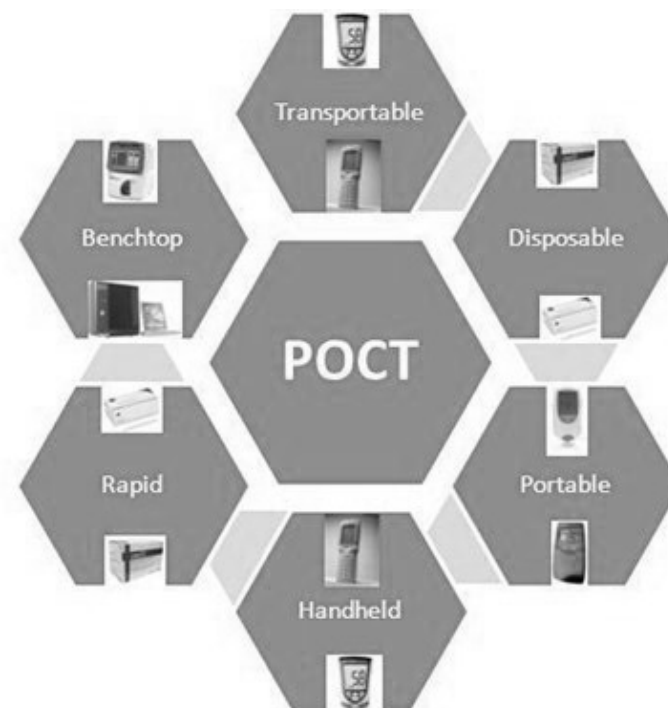


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1.2 Definition of POCT

ISO 15189:2022

“Diagnostic testing that is performed **near to or at the site** of the patient care with the result leading to possible **change in the care** of the patient”



1.3 Current applications of POCT

Central lab versus POCT method



- ✓ Complex infrastructure
- ✓ Large instruments
- ✓ Automation
- ✓ High volume testing
- ✓ TAT 1/2-1-2 hours



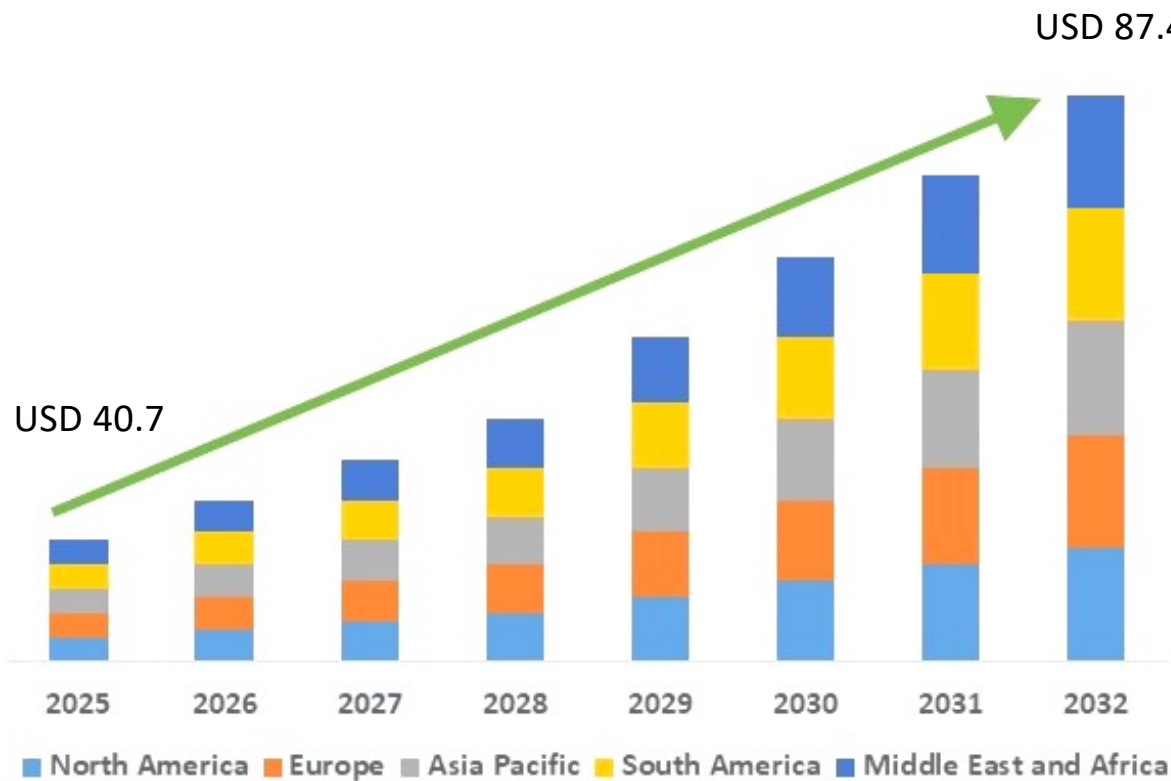
- ✓ Miniaturization: microsensors
- ✓ Low complexity, user friendly
- ✓ Low volume testing
- ✓ TAT in minutes



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1.3 Current applications of POCT

Impact on IVD market



- ✓ Personalized medicine
- ✓ Aging populations
- ✓ Decentralisation of testing supported by innovations in mobile health

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Source: Data Bridge market Research Market Analysis study 2025

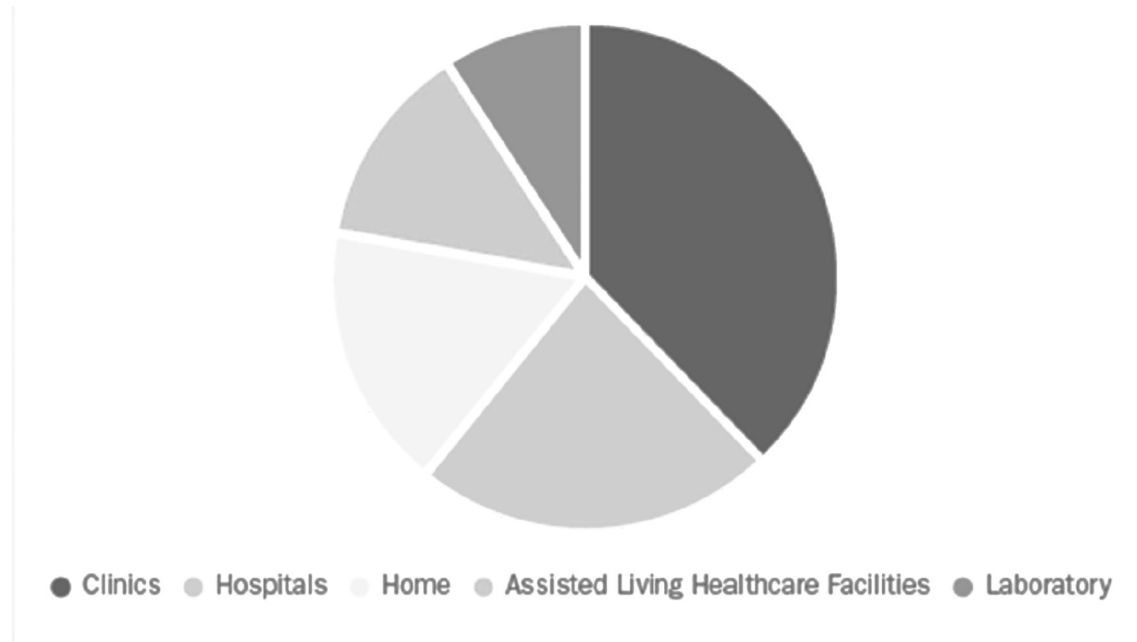
1.3 Current applications of POCT

Geographic spread



1.3 Current applications of POCT

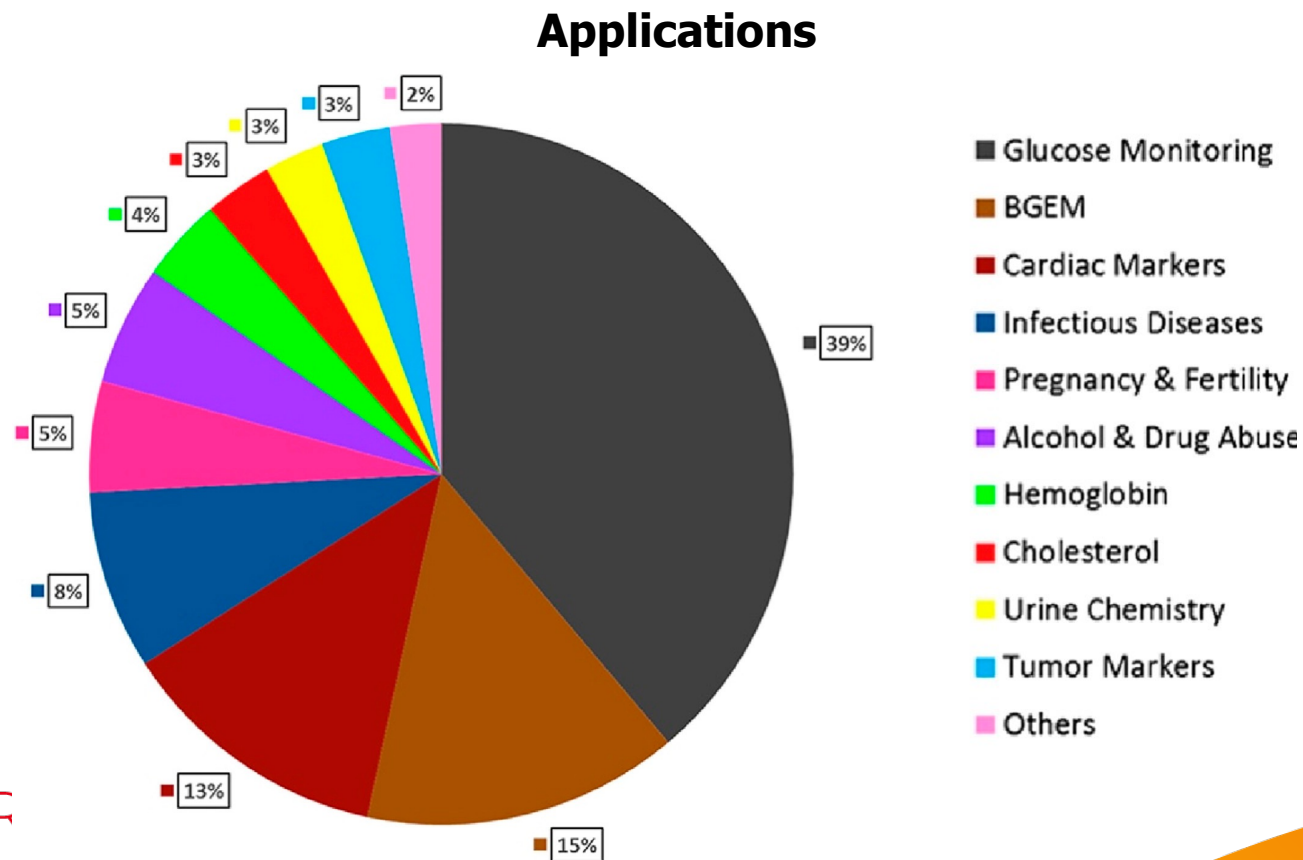
End-use setting



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Khan AR *et al.* Front Lab Chip 2024; 3: 1394752

1.3 Current applications of POCT



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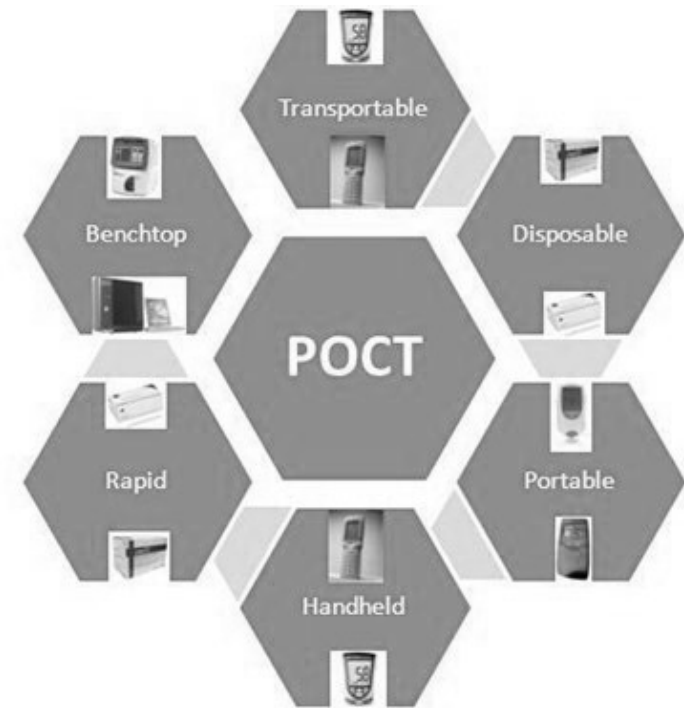
Sachdeva *et al.* Front Bioeng Biotechnol 2022; 8: 602659

1.3 Current applications of POCT

ISO 15189:2022

"Diagnostic testing that is performed **near to or at the site** of the patient care with the result leading to possible **change in the care** of the patient"

- ✓ **Proven effectivity** on direct medical acting
- ✓ **Analytical and clinical reliability** of the POCT as compared to the central lab test
- ✓ **User friendly** without increasing workload

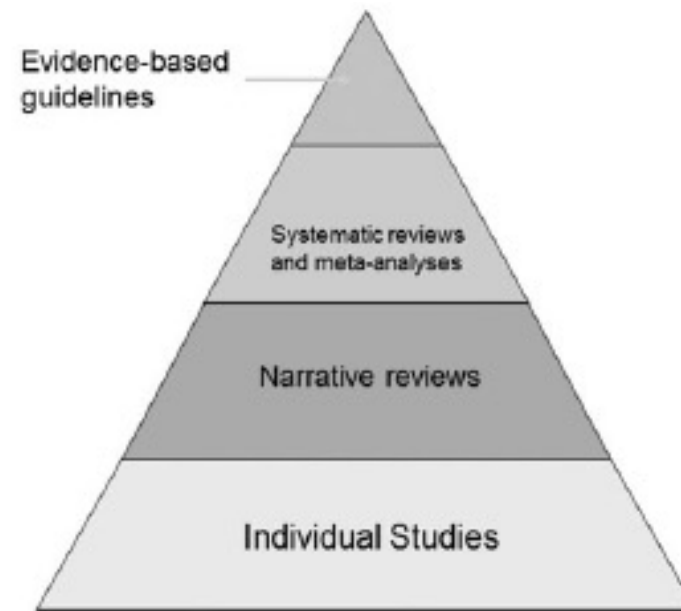


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ISO 15189:2022

1.4 Proven effectivity

Evidence based introduction of POCT



1.4 Proven effectivity

POCT at the emergency department



POCT at ED has the potential to

- allow initiation of correct treatments
- improve clinical outcomes
- ensure patients are conveyed to best suited facility

Systematic review and metanalysis (n=3410)

- POCT tends to lower LOS (not significantly)

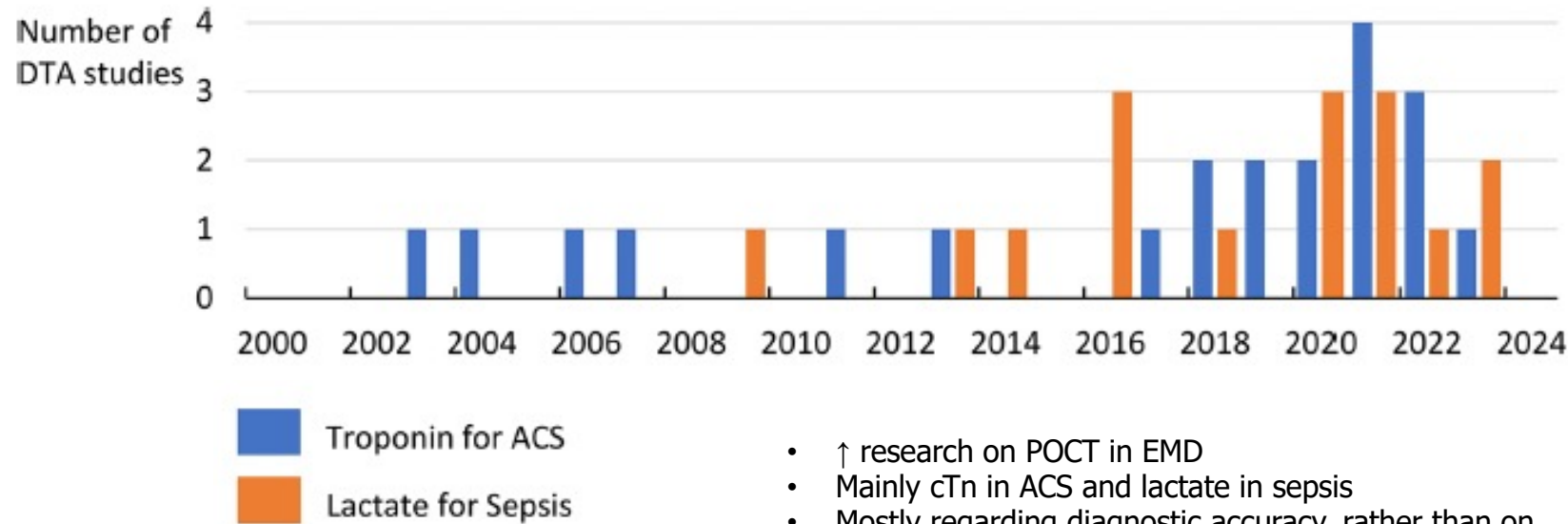
Biomarker dependent/in-bedded in fast-track strategies



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1.4 Proven effectivity

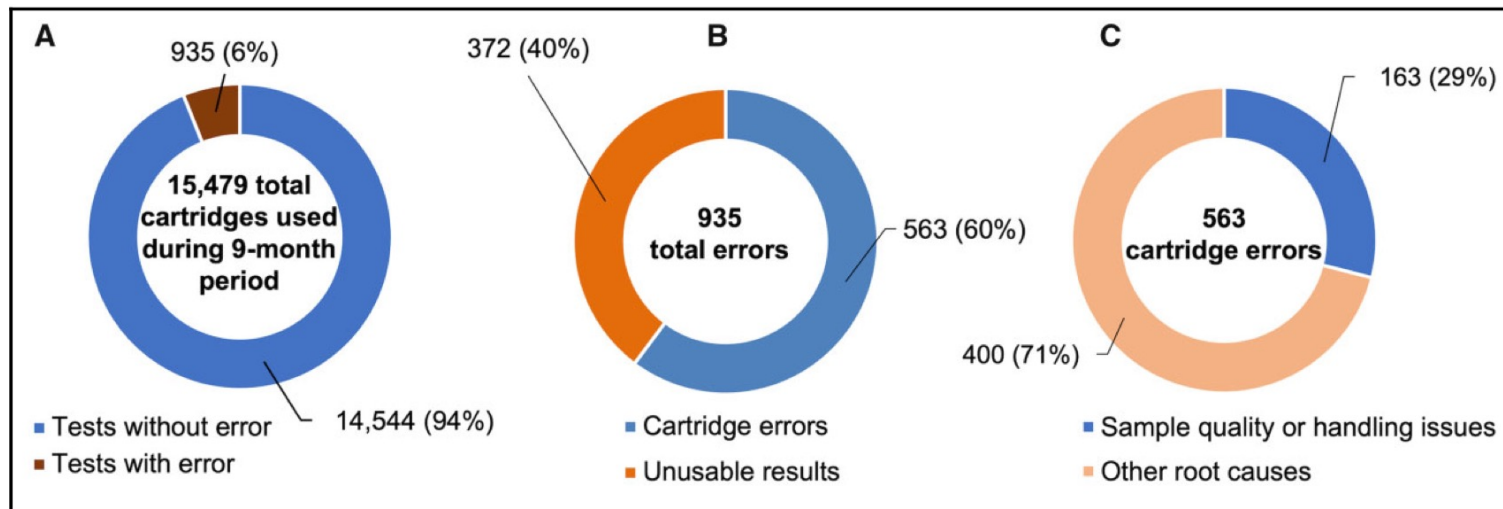
Evolution of POCT ED research



- ↑ research on POCT in EMD
- Mainly cTn in ACS and lactate in sepsis
- Mostly regarding diagnostic accuracy, rather than on **clinical effectiveness, acceptability and economic effectiveness**

1.4 Proven effectivity

POCT at ED: Economical impact



- LOS significantly longer with erroneous POCT results
- Direct costs = 45.000\$
- Indirect costs = 486-729 hours of avoidable nursing labor
- A stringent **QA (<lab) program** could overcome these issues

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Kazmierczak *et al* J Appl Lab Med 2022; 7: 650-660
Auvet *et al*. Ann Intensive Care 2016; 6: 57

1.4 Proven effectivity

EUSUM/EuSEN/EFLM guidelines

Question 15: What is the effect of POCT for the working process in the ED, using TAT as the main outcome?

Recommendation

We recommend POCT as one possibility to reduce the total TAT after interdisciplinary risk/benefit analysis and definition of an appropriate quality control program, regular staff training and documentation (e.g. by connecting devices to the Hospital- or Laboratory information system).

Quality of the evidence

Overall quality of evidence for the endpoint TAT is VERY LOW.

Strength of the recommendation

A weak recommendation in favour of implementing POCT, when using TAT as the outcome; 2D GRADE.



! POCT straightforward for: Blood gas, electrolytes, glucose, lactate

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Garcia-Castrillo *et al.* CCLM 2024; 62: 1538-1547

1.5 Analytical performance

Differences central lab-POCT method



- ✓ Very high **analytical accuracy**
 - ✓ traceability to higher order reference materials
- ✓ Very **precise** (CV < 5%)
- ✓ Low **LoD** -> early detection possible

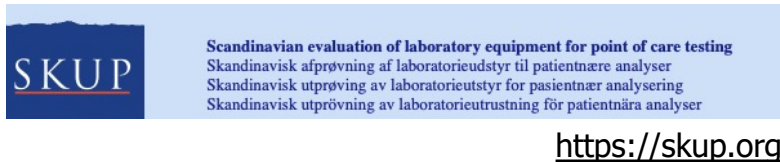
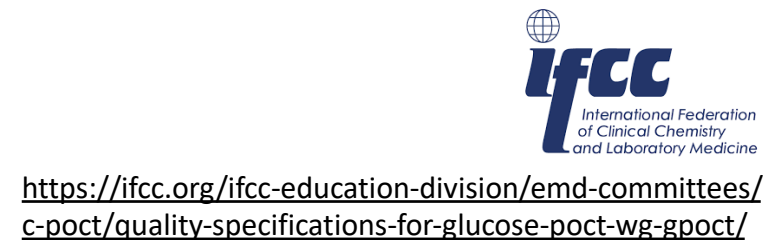
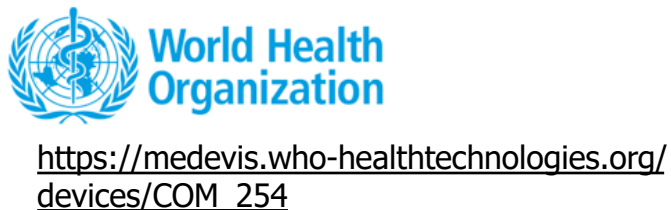


- ✓ Lower **analytical accuracy**
 - ? traceability to higher order reference materials
- ✓ Less **precise** (CV > 10%)
- ✓ Higher **LoD** -> may miss small increases

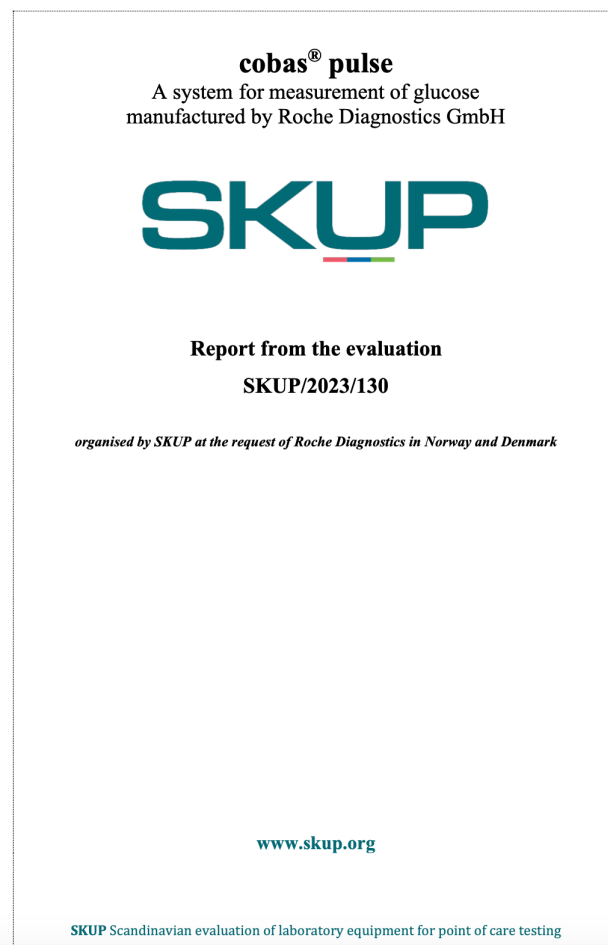


1.5 Analytical performance

Validation/verification protocol and acceptance criteria

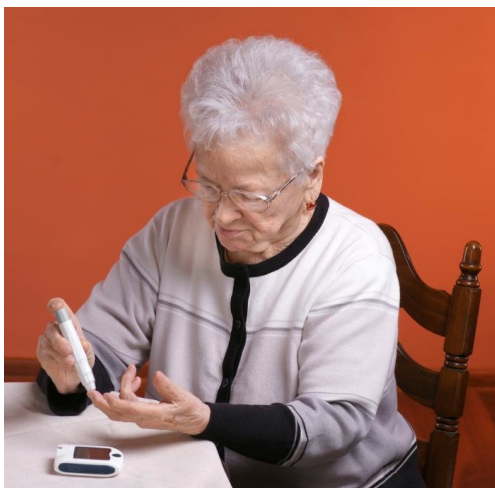


1.5 Analytical performance



1.5 Analytical performance

Impact of POCT setting



Home testing



Care facility



Critical care

Quality requirements



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IFCC. CCLM 2013: 51: 943-952

1.5 Analytical performance

Impact of POCT setting: Method comparison POCT glucoses versus hexokinase

Glucose	ISO 15197 2003	ISO 15197 2013 EN ISO 15197:2015	CLSI POCT12-A3 2013*	FDA 2020
Cutoff (mg/dL)	75	100	100	75
Criterion				
< cutoff	± 15 mg/dL	± 15 mg/dL	± 12,5 mg/dL	± 12 mg/dL
≥ cutoff	± 20%	± 15%	± 12,5%	± 12%
Coverage (%)		95 max. 1% > 20% = zone A/B consensus error grid	95 max. 2% > 20%	95 max. 2% > 15%

*IFCC 2017. Glucometer at critical care



Quality requirements

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WHO MeDeVis 2025; IFCC Working Group GMECC: 10/12/2017
EN ISO 1597:2015; FDA Guidance, 2020; CLSI POCT12-A3: 2013

1.5 Analytical performance

Continuous QA: iQC

Device

Name
SP-PULSE066-401663

Serial No.
A101012030

Type
cobas pulse

Location
SP - GERIATRIE

Result details



Result
↑ 76,0 mg/dL

Target
59,0 mg/dL

Date
27/03/2025

Alarms
▲ A3AK, OC, QCOR

Test
GLU OT A3: Level 1

Range
47,0 - 71,0 mg/dL

Time
00:01

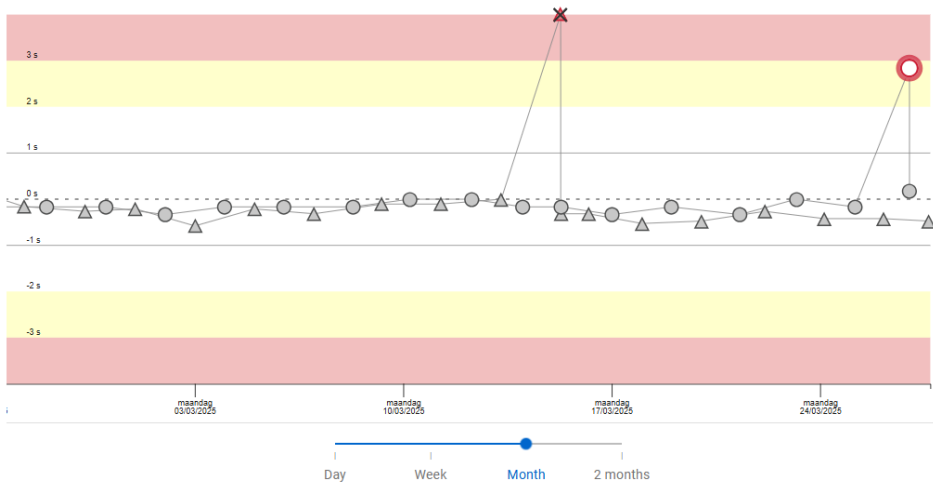
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📝 slechte staalaanbr (Operator comment)

Accept

Reject

By device By operator By material



- **Based on risk analysis and guidelines**

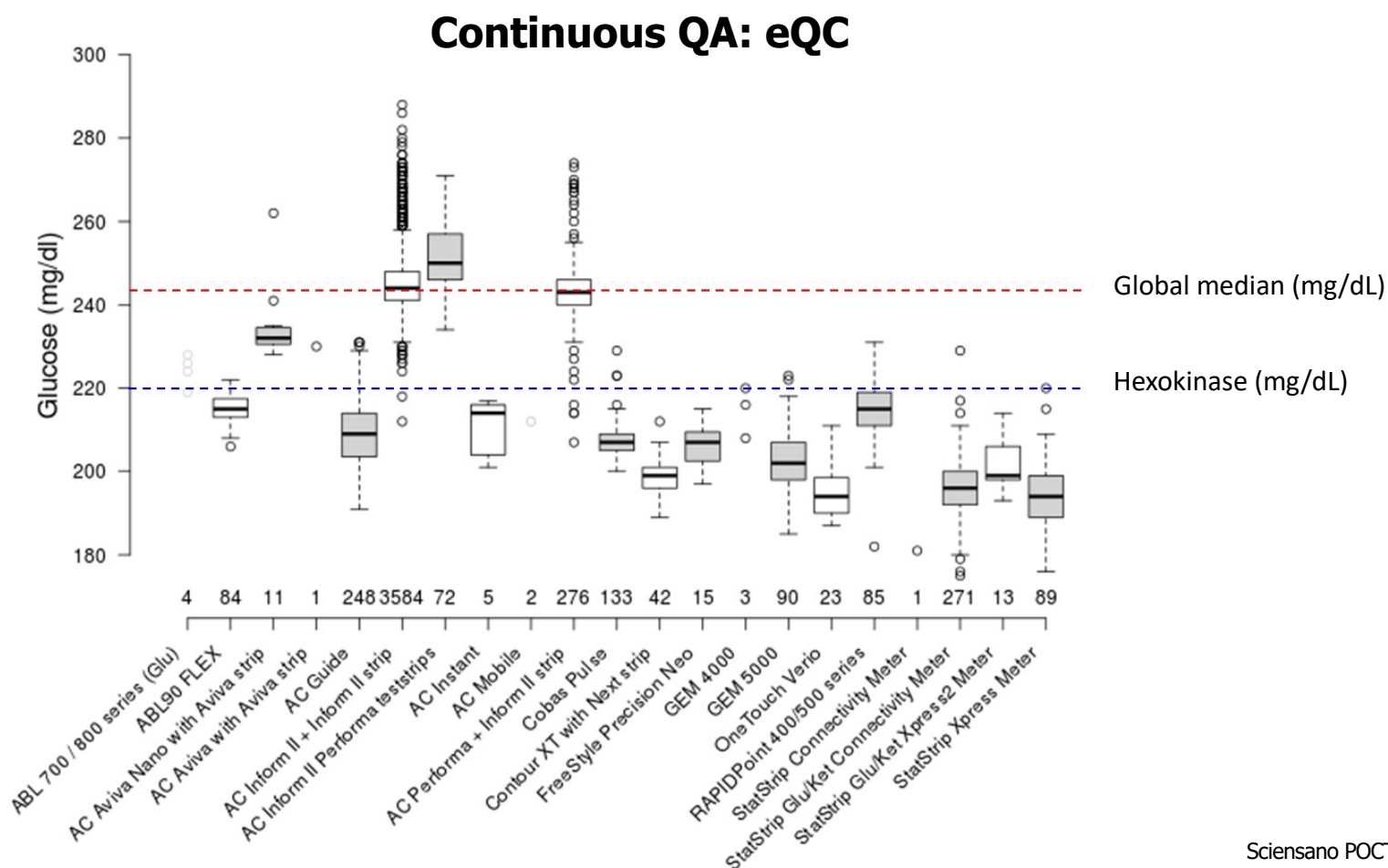
- Number of analyses performed
- (in)stability of the POCT test proces
- Type of iQC material (human/artificial)
- Number and which concentration levels
- Analytical performance criteria

- **Route cause analysis**

- iQC violation = blocking result reporting
- iQC errors => route cause analysis by POCT-team

Gidske *et al.* Clin Chem Lab Med 2022; 60: 740-747
Stavelin *et al.* Crit Rev Clin Lab Sci 2024; 61: 164-177

1.5 Analytical performance



1.6 User friendliness

All end-users

- **Why:** End-users are **NO** lab technicians
- **GOAL:** optimizing the whole test process to enable best use of end-users' time, to focus on other clinical priorities
- **End-user evaluation** < method verification/validation new POCT



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1.6 User friendliness

Training

- **New operator/New instrument**

- In-person training by POCT team
 - 'Train the trainer'
 - Department meetings
 - Ppt/instruction movie
- Focus on **operator errors**
- Individual login

- **Periodically**

- Recertification
- Period of inactivity
- Periodical activity verification (# tests performed)
< Feedback for POCT committee
- Objective recertification criteria:
e.g. min. POCT activity
e-questionnaire with min. score



6. Hoe lang gaat een volledig opgeladen batterij mee? (1 punt) *

☐ Ongeveer 2 uur

☐ Ongeveer 12 uur

☐ Ongeveer 24 uur

7. Het toestel geeft een error na het inbrengen van de strip en vraagt om een nieuwe strip te gebruiken. Mag ik dezelfde ongebruikte strip gebruiken of neem ik een volledig nieuwe uit het potje? (1 punt) *

☐ Ja, ik mag dezelfde strip gebruiken, want deze is toch niet gebruikt.

☐ Neen, er moet steeds een nieuwe strip gebruikt worden, want mogelijk is er iets mis met de strip, zelfs als deze nog niet gebruikt is.

8. Waarom mag ik de strip niet manueel verwijderen? (Alle juiste antwoorden aanduiden.) (1 punt) *

☐ Het kan interne schade veroorzaken wanneer ik de strip manueel verwijder.

☐ De strip aanraken geeft kans op elektrische schokken.

☐ Door de ejectieknop op het toestel

9. Ik heb 2 pogingen gedaan om de QC uit te voeren en het lukt me niet en ik moet een dringende patiëntentest uitvoeren. Wat doe ik ? (Alle juiste antwoorden aanduiden) (1 punt) *

☐ Ik vraag mijn collega om de QC nogmaals uit te voeren. Misschien is het gewoon niet mijn dag.

☐ Ik kan 1 dringende test (stat of cyto test) uitvoeren.

☐ Ik doe de QC test met een nieuwe flacon controle reagens.

☐ Gisteren lag de QC nog goed, dus dat zal wel niet zo erg zijn.

10. Wat zijn de kritische glucosewaarden? (1 punt) *

☐ < 60 ; > 110

☐ < 50 ; > 400

☐ < 50 ; > 600



2. POCT regulations and guidelines



2. POCT regulations and guidelines

European Regulation (=Legislation= manufacturer's must do)

POCT-instruments are classified as in vitro diagnostic medical devices (IVD) and, as a consequence, they are regulated according to the **European IVD-directive**.

European Union **Directive** 98/79/EC (IVDD)  European Union **Regulation** 2017/746/EC (**IVDR**)

1. Move to **risk-based classification** from previous list-based classification: low risk (Class A) up to high risk (Class D). Depending on the intended purpose specified by the manufacturer CRP POCT devices will likely be in Class C or Class B.

Detailed requirements for the **performance evaluation**:

- Scientific validity
- Analytical performance
- Clinical performance

2. IVDs for POCT must perform appropriately for their intended purpose taking into account the skills of **the intended user** and the potential variation in the user's technique and environment

3. **Post market** surveillance plan

2. POCT regulations and guidelines

International accreditation guidelines

Accreditation programs: CLIA, CAP, JCI (Joint Commission International), COLA

↓ **hospital**

ISPG (International patient safety goals) and AOP (Assessment of patients)
IPSG.2 Through IPSG.2.2
AOP 5.1-5.2-5.5

ISO 15189:2022

↓ **lab**
Annex A



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2. POCT regulations and guidelines

International guidelines

CLSI guidelines (N=17)

CLSI serves as the American National Standards Institute (ANSI)-appointed Secretariat for the International Organization for Standardization (ISO) Technical Committee 212 (ISO/TC 212), Clinical laboratory testing and in vitro diagnostic test systems.

CLSI POCT01

Point-of-Care Connectivity

CLSI POCT04

Essential Tools for Implementation and Management of a Point-of-Care Testing Program

CLSI POCT07

Quality Management: Approaches to Reducing Errors at the Point of Care

CLSI POCT14

Point-of-Care Coagulation Testing and Anticoagulation Monitoring

CLSI POCT09

Selection Criteria for Point-of-Care Testing Devices

CLSI POCT17

Use of Glucose Meters for Critically Ill Patients

2. POCT regulations and guidelines

Belgian legislation clinical laboratories



Legislation

KB 3/12/1999 < **PRL 2025**

Visitations



COMMISSIE VOOR KLINISCHE BIOLOGIE
WERKGROEP PRAKTIJKRICHTLIJN

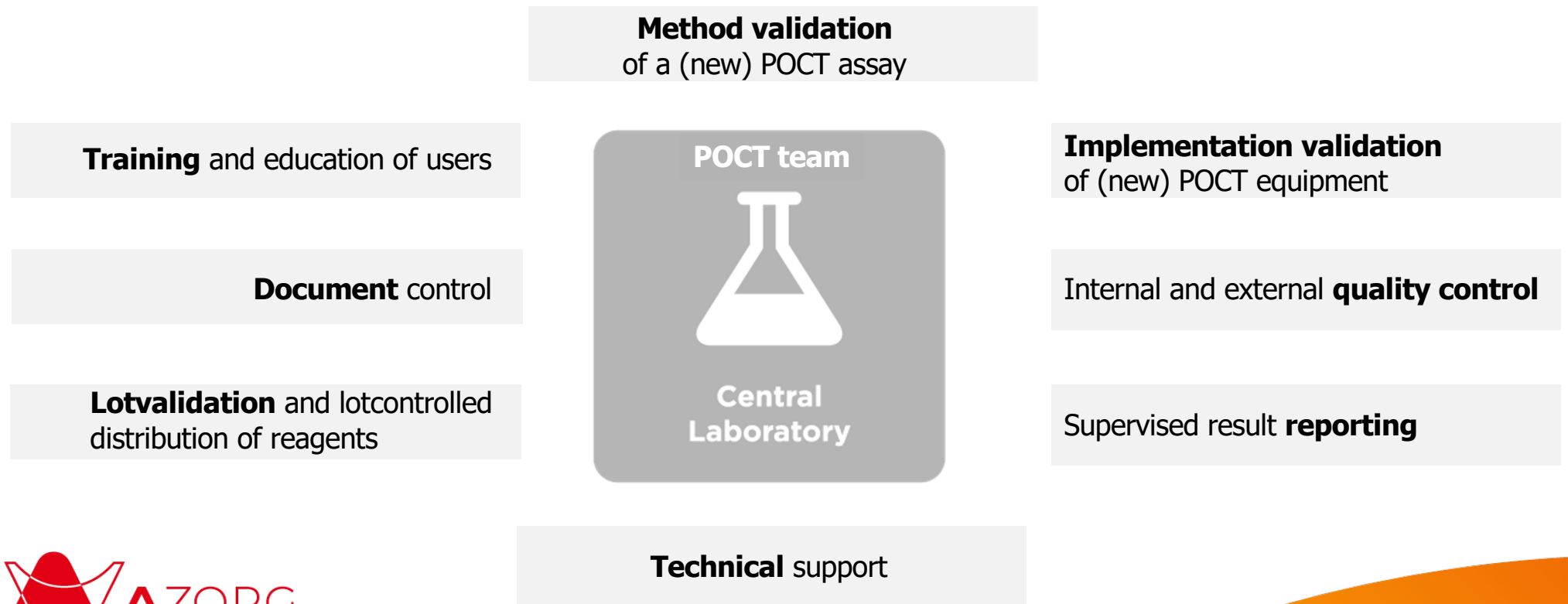
PRAKTIJKRICHTLIJN VOOR
HET OPZETTEN VAN EEN
KWALITEITSSYSTEEM IN
DE ERKENDE
LABORATORIA VOOR
KLINISCHE BIOLOGIE

POCT = **dedicated Chapter 9**, with accents

All other PRL chapters do apply too

9	Eisen voor point-of-care testen (POCT)	122
9.1	Algemeen	122
9.2	Bestuur	122
9.3	Kwaliteitsborgingsprogramma	122
9.4	Trainingsprogramma	123

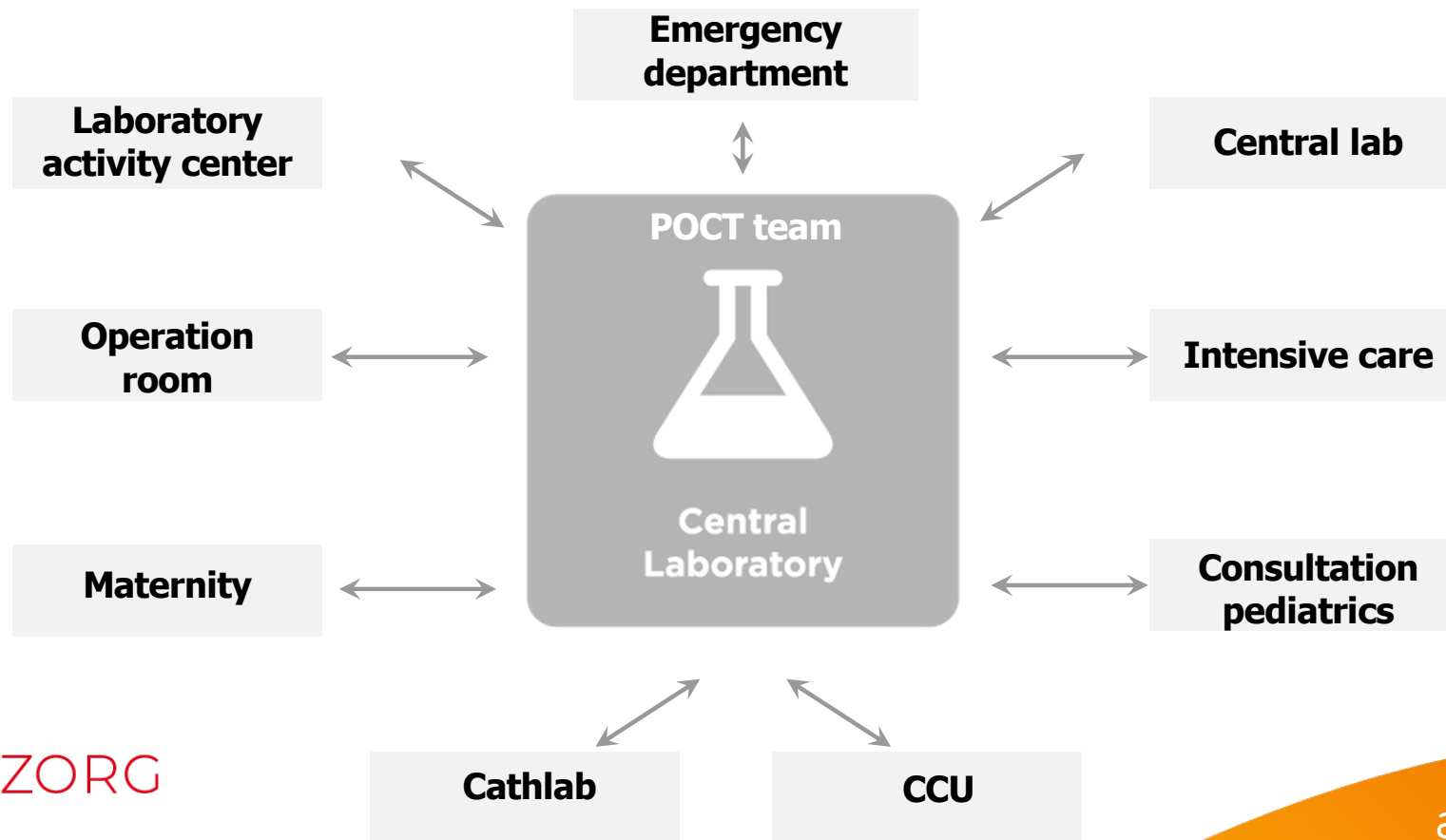
2.1 Role of the laboratory in POCT



2.1 Role of the laboratory in POCT



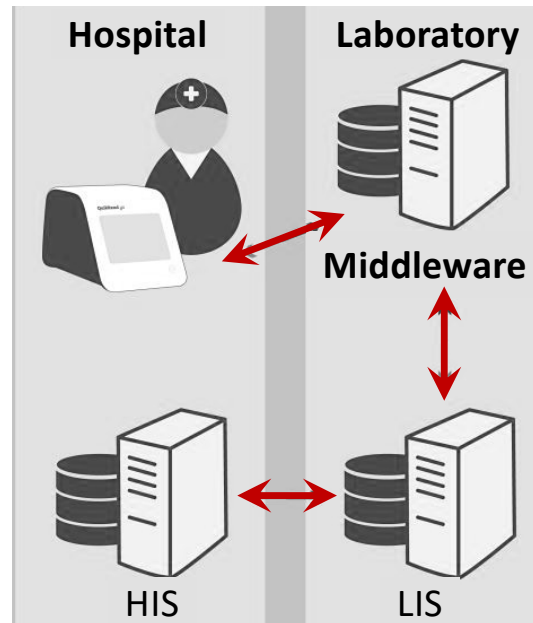
2.1 Role of the laboratory in POCT





2.1 Role of the laboratory in POCT

Importance of connectivity



Bidirectional connection POCT <> lab middleware

Transfer:

- patient data (ADT; demography, ward)
- test results
- iQC results
- POCT instrument status
- POCT user data

2.2 Governance of POCT within the lab

Laboratory POCT **T.E.A.M.**

Lab director

End responsibility

Clinical biologists

multidisciplinary

POCT coordinator

daily quality assurance

Competent POCT lab technicians

POCT reference nurses

Hemovigilance team

24h/24h 7d/7d governance



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PRL KB versie 4 – 2025; 6.2

2.3 Governance of POCT outside the lab

POCT committee

Multidisciplinary

Organization management

medical director
e.g. staff worker QA
staff worker nursing departement

Laboratory medicine

Laboratory POCT team

Clinicians

medical representatives of the departments using POCT
e.g. Emergency departement
ICU
Endocrinology



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PRL KB versie 4 – 2025; 9.2

2.3 Governance of POCT outside the lab

POCT committee

Multidisciplinary

Aim

State-of-the-art POCT implementation
Accuracy & efficiency
Continuous quality assurance
Reporting of use
Reflection of needs

((Inter)national)) POCT projects

Responsibilities

Organisation-wide service level agreement

Frequency

Frequency based on organizational needs
at least 1x/year

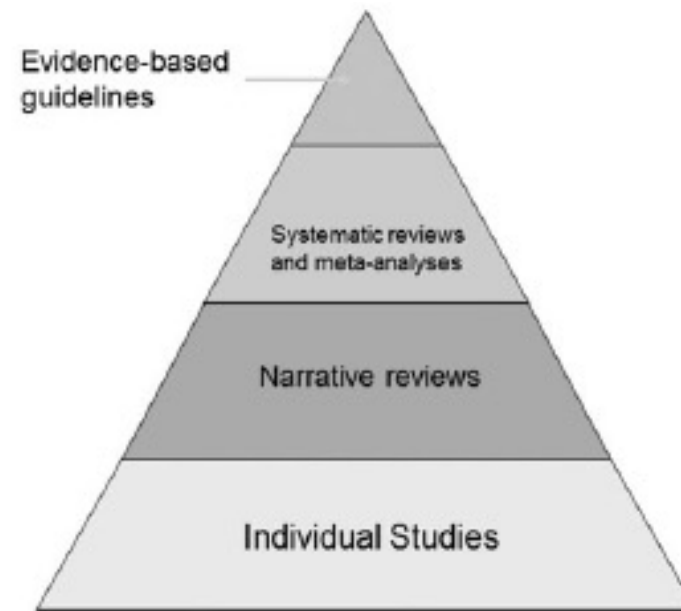


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PRL KB versie 4 – 2025; 6.7 en 9.2

2.4 POCT Governance aim

Evidence based introduction of POCT



2.4 POCT Governance aim

POCT benefits

- ✓ Rapid results, rapid decision-making.
- ✓ Reduction of time associated with pré and post-analytics.
- ✓ Faster therapeutic intervention.
- ✓ Early recognition of critical situations.
- ✓ Raptid patient stratification in emergency care.
- ✓ Easy interpretation.
- ✓ Smaller sample volume. Capillary sample.
- ✓ Portability.
- ✓ Reduction of overall costs (indirect costs).

POCT challenges

- ✓ Many and diverse users. High turnover.
- ✓ Ongoing training.
- ✓ Connectivity. Poor patient identification.
- ✓ Quality assurance of results.
- ✓ Proper accuracy and precision.
- ✓ Patient safety.
- ✓ Maintenance of devices. Reagents.
- ✓ Cost of testing, usually higher than central lab.
- ✓ Determination.

2.4 POCT Governance aim

EUSUM/EuSEN/EFLM guidelines

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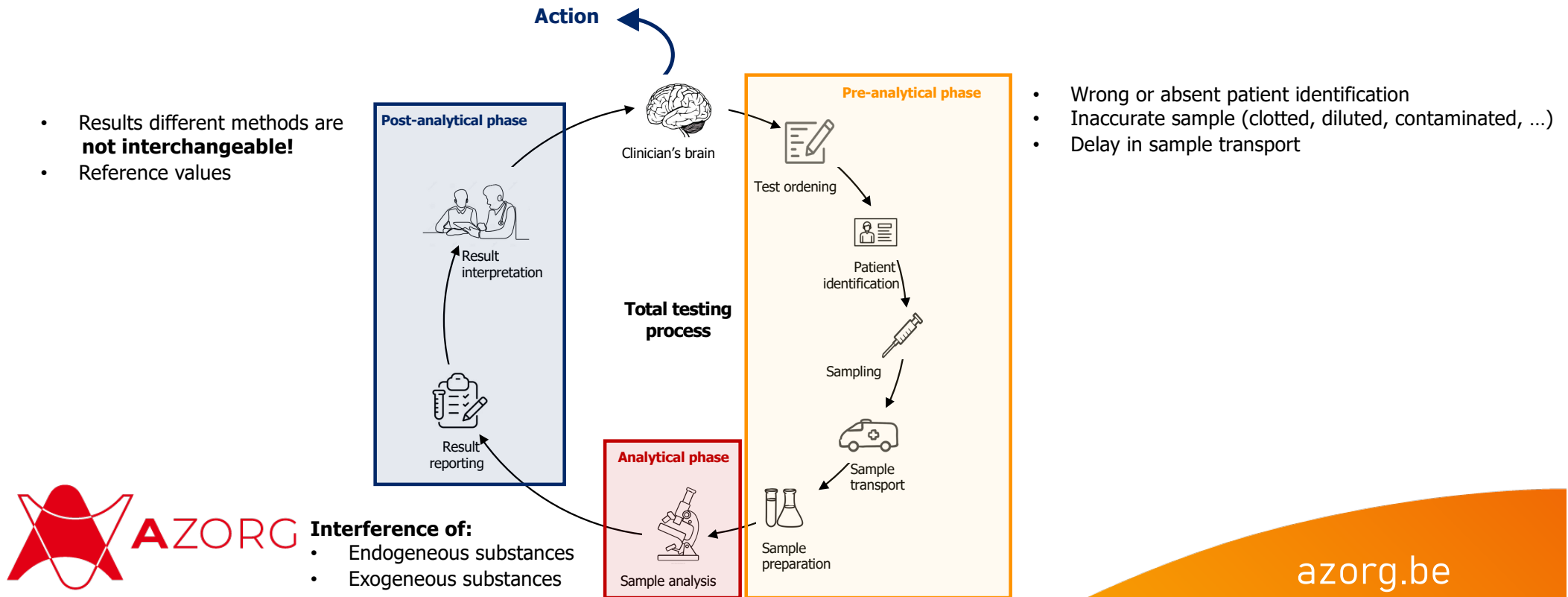
! POCT straightforward for: Blood gas, electrolytes, glucose, lactate

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Garcia-Castrillo *et al.* CCLM 2024; 62: 1538-1547

2.4 POCT Governance aim

Impacting whole test process



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Interference of:

- Endogenous substances
- Exogenous substances

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Satheesh *et al.* Cureus 2025; 17: e80499

2.4 POCT Governance aim

Confounder inventarization

- **Risk analysis**

Satheesh *et al.* Cureus 2025; 17: e80499
Van Hoof *et al.* CCLM 2022; 60: 1186-1201

- Multidisciplinair team (clinician, lab, nurse, ...)
- Whole test process
- Focus= patient safety (e.g. FMEA)
- Periodically revision needed

- **Definition of KPI**

Shaw *et al.* CCLM 2023; 61: 1280-1287

- Objectifying risks/opportunities
E.g use of % hemolysis (parallel GBA – CL analysis)
% error codes
% patient ID registration
% iQC errors
% critical results repeated by POCT/lab method



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PRL KB versie 4 – 2025; 5.6 en 8.8

2.4 POCT Governance aim

Confounder inventarization: practical example



MUG, PIT, MIG



Lab <> EMD

- Result registration
- iQC registration/follow-up
- Certification
- Lot validation/Reagent supply



Size
Battery capacity



Other teststriip
No connectivity

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2.5 Regulation of POCT users

Belgian legislation



- **Physicians**
- **Medical laboratory technician**
- **Nurses**

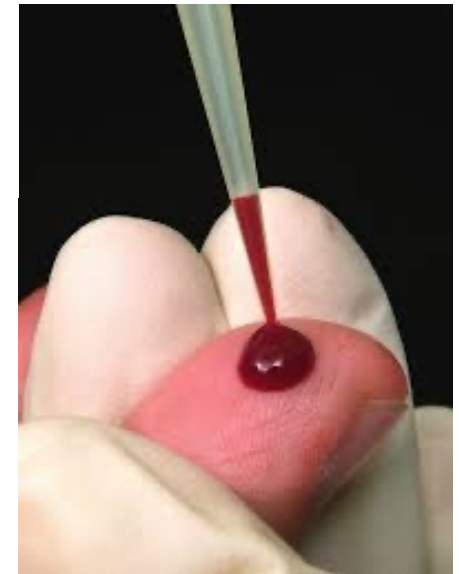
Reference: KB 20/09/2023: 'KB bepalende de lijst van de verpleegkundige technische verstrekkingen betreffende de basisverpleegkundige, alsmede hun uitoefeningsvoorwaarden'

- **Practice assistant**

Reference: KB 26/11/2023: 'KB betreffende het beroep van praktijkassistent'

- **Nursing assistant**

Reference: www.departemetnzorg.be/nl/welke-taken-mag-ik-uitvoeren-als-zorgkundige



2.6 Regulation of POCT in primary care?

Belgian legislation

POCT is emerging outside the hospital:

- Primary care cabinet
- Nursing homes
- ...



No legal framework



- No reimbursement
- Risking doubtful quality of equipment
- Lack of training = error risk
- No traceability of results or users
- Risk of over- or underuse of tests

2.6 Regulation of POCT in primary care?

Evidence?

THE LANCET

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ARTICLES · [Volume 406, Issue 10512](#), P1599-1610, October 11, 2025 [Download Full Issue](#)

A clinical decision tool including a decision tree, point-of-care testing of CRP, and safety-netting advice to guide antibiotic prescribing in acutely ill children in primary care in Belgium (ARON): a pragmatic, cluster-randomised, controlled trial

[Jan Yvan Verbakel, PhD](#) ^{a,b,†} [✉](#) · [Ruben Burvenich, PhD](#) ^{a,b,c,†} · [Erinn D'hulster, MSc](#) ^{a,b,e} · [Liselore De Rop, MD](#) ^{a,b} · [Ann Van den Bruel, PhD](#) ^b · [Sibyl Anthierens, PhD](#) ^{e,f} · et al. [Show more](#)

- ✓ 171 primary care practices in Belgium
- ✓ 6750 children (6m-12y)
- ✓ FU: 30 days
- ✓ 1st outcome: AB prescription



The clinical decision tool reduced antibiotic prescribing in children without causing harm. Our results support its broader dissemination and implementation to improve the management of acutely ill children in ambulatory care.

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Verbakel *et al.* Lancet 2025; 406: 1599-1610

2.6 Regulation of POCT in primary care?

Evidence?



**Cochrane
Library**

Cochrane Database of Systematic Reviews

**Biomarkers as point-of-care tests to guide prescription of antibiotics
in people with acute respiratory infections in primary care (Review)**

Smedemark SA, Aabenhus R, Llor C, Fournaise A, Olsen O, Jørgensen KJ

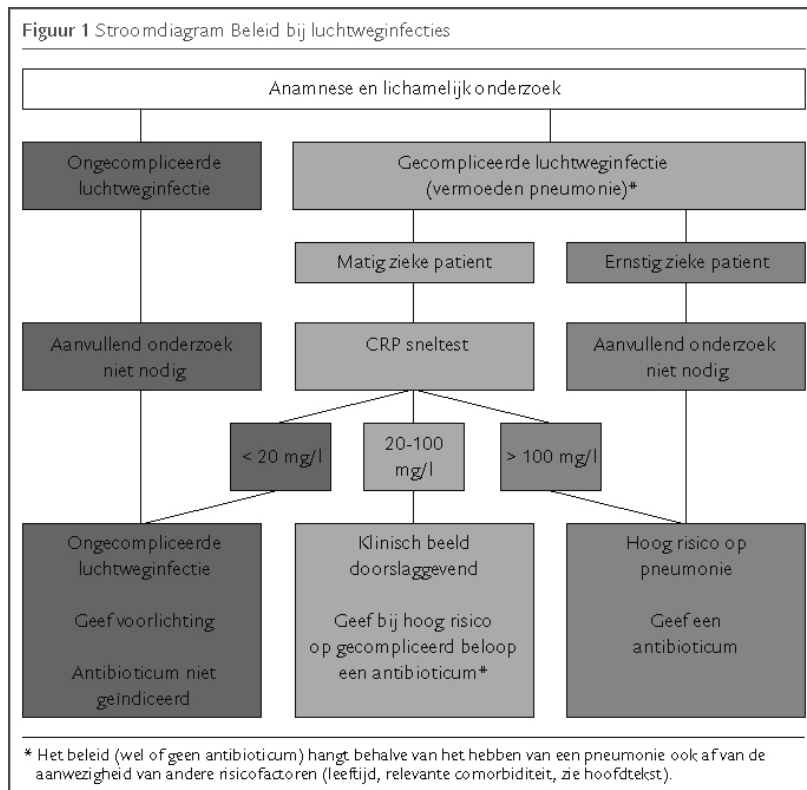


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Smedemark SA *et al.* CDSR 2022;10

2.6 Regulation of POCT in primary care?

Dutch references



NHG-Standaard Acuut hoesten (M78)

NHG-werkgroep:

De Bont EGPM, Greving JP, Kurver MJ, Van der Mooren FM, Van de Pol AC, Prins JM, Schot MJC, Verheij ThJM, Weersma RLS.

Versie 3.3, juli 2025

Jones *et al.* BMH Family Practice 2013; 14: 117
Hardy et al. BMJ Open 2017; 7

2.6 Regulation of POCT in primary care?

Dutch references

RICHTLIJN
POINT OF CARE TESTING (POCT) IN DE HUISARTSENZORG

Hopstaken RM¹, Kleinveld HA², Balen van JAM³, Krabbe JG⁴,
Broek van den S⁵, Weel J⁶, Slingerland RJ⁶, Ruiter C⁷, Kusters GCM⁸
¹Salto Diagnostisch Centrum Utrecht, ²Atrium MC Heerlen,
³NHG Utrecht, ⁴Medlon Enschede/Almelo, ⁵Izore Leeuwarden,
⁶Isala Zwolle, ⁷NVVC Verenigingsbureau Utrecht,
⁸Jeroen Bosch Ziekenhuis 's-Hertogenbosch

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genootschap

centra voor
medische
diagnostiek

Nederlandse Vereniging
voor Klinische Chemie
en Laboratoriumgeneeskunde

Medische
Microbiologie



NHG-Standaard
Acuut hoesten (M78)

NHG-werkgroep:
De Bont EGPM, Greving JP, Kurver MJ, Van der Mooren FM, Van de Pol AC, Prins JM, Schot MJC, Verheij ThJM, Weersma RLS.

Versie 3.3, juli 2025



NHG-Standaard
Acuut coronair syndroom (M80)

NHG-werkgroep:
Auwerda A, Bouma M, Bruins Slot M, Cohen M, Damman P, de Roy van Zuijdewijn F, Greving J, Rutten F, Van Casteren B, Wichers I, Willemsen R, Woudstra P

Versie 3.1, juli 2025



NHG-Standaard
Diepveneuze trombose en
longembolie (M86)

NHG-werkgroep:
Geersing GJ, Kessel LS, Poldervaart JM, Sival PPE, Smits PLM, Thissen LGP, Van den Donk M, Van Nieuwenhuijze FM, Van Osselen ECM, Wichers IM.

Versie 4.1, september 2024



NHG-Standaard
Het soa-consult (M82)

NHG-werkgroep:
AB E, Bruggeling NM, Donker GA, Posthuma J, Schep A, Stam AJ, Swarte CME, Van der Spruit R, Wittenberg J.

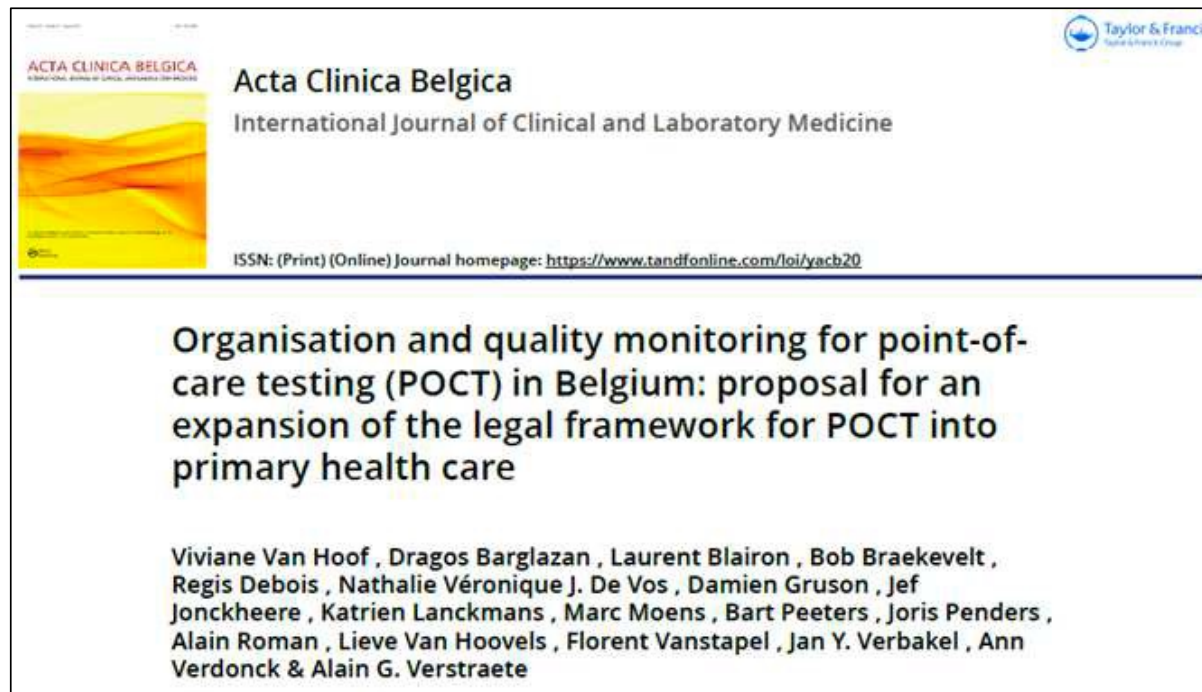
Versie 3.2, januari 2025

2.6 Regulation of POCT in primary care?



2.6 Regulation of POCT in primary care?

White paper



Draft legal framework for POCT issued by the Working Group on POCT and on Legislation from the National Commission on Clinical Biology

azorg.be

Van Hoof *et al.* Acta Clin Belg 2022; 77: 329-336

3. Conclusion

- **POCT in Belgium**
 - reimbursed in hospital setting only
 - Continuous QA by the central laboratory (!connectivity)
- **POCT = TEAM WORK**
 - Multidisciplinairity is of utmost importance
 - All stake holders should be involved
BEFORE/MEANWHILE POCT is implemented
- **POCT = NOT ALWAYS THE BEST SOLUTION**
 - Identify confounders, risk analysis based
 - User friendly
- **POCT outside the hospital: (intensive) work in progress**



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Garcia-Castrillo *et al.* CCLM 2024; 62: 1538-1547

Thank you!



Colleagues Clinical Biologists AZORG
Members POCT committee AZORG
24/24 POCT team AZORG (all sites)



Expert commission POCT Sciensano
Co-chair of POCT expert working group
of National Commission Clinical Biology



IFCC POCT working group



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