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NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

Implementing IVDs in community healthcare: challenges and possible solutions

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NIHR HRCs

Lead NHS Organisation	Area of focus
1. Newcastle upon Tyne NHSFT	Dx, ID, multimorbidity
2. Leeds Teaching NHSFT	Surgical and rehab
3. Sheffield Children's NHSFT	CYP Health
3. Sheffield Teaching NHSFT	LTCs, DM, nephro, women's
4. Manchester U NHSFT	Urgent and emergency
5. Notts Healthcare NHSFT	Mental health
5. Nottingham U NHSFT	Rehab and assistive tech
6. UH Birmingham NHSFT	Trauma and emergency
7. Cambridge U NHSFT	Brain and spine injury
8. Oxford Health NHSFT	Community healthcare
9. Guy's & Tommy's NHSFT	Cardio and respiratory
9. Imperial Healthcare NHST	Dx for cancer, ID, resp, crit
9. SLaM NHSFT	Dementia and brain health
10. Royal Devon U NHSFT	Dx, rehab and frailty

NIHR HRC in Community Healthcare: Collaboration across the breadth of community healthcare research and delivery

Clinical Director – Professor Gail Hayward

Co-Director – Professor Chris Butler

Nuffield Department of Primary Care Health Sciences, University of Oxford

Outline

- Why implement point-of-care IVDs (POCT) in the community?
- Usage and desired access to POCT
- Critical domains for implementation of POCT in community care
- Challenges
  - Evidence of clinical performance
  - Maintenance of POCT service quality
  - Practical considerations for deployment
  - Funding

Why implement POCT in the community?

- May improve patient access to testing / allow opportunistic testing
  - Health checks
  - Diagnoses associated with stigma
- Antimicrobial stewardship
- Step-down invasiveness of testing
  - Venous to finger-stick
- Facilitate remodelling of diagnostic and monitoring pathways deployed through community care
  - HF diagnosis and drug titration
  - INR
- Could support HM Government's aspirations to move more care from hospital to community

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Usage and desired access to POCT

Typical point-of-care ‘medtech’ in a UK GP surgery in 2025

- Thermometer 1714
- Stethoscope 1816
- Sphygmomanometer 1881
- Pulse oximeter 1978
- Dipstick Urinalysis 1956
- LFD urine pregnancy test 1988

Open Access Research

BMJ Open

Current and future use of point-of-care tests in primary care: an international survey in Australia, Belgium, The Netherlands, the UK and the USA

Jeremy Howick,[1] Jochen W L Cals,[2] Caroline Jones,[1] Christopher P Price,[1] Annette Plüddemann,[1] Carl Heneghan,[1] Marjolein Y Berger,[3] Frank Buntinx,[2,4] John Hickner,[5] Wilson Pace,[6] Tony Badrick,[7] Ann Van den Bruel,[1] Caroline Laurence,[8] Henk C van Weert,[9] Evie van Severen,[4] Adriana Parrella,[8] Matthew Thompson[10]

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Howick *et al., BMJ Open, 2014*
https://doi.org/10.1136/bmjopen-2014-005611

GP reported use of POCT – 2014

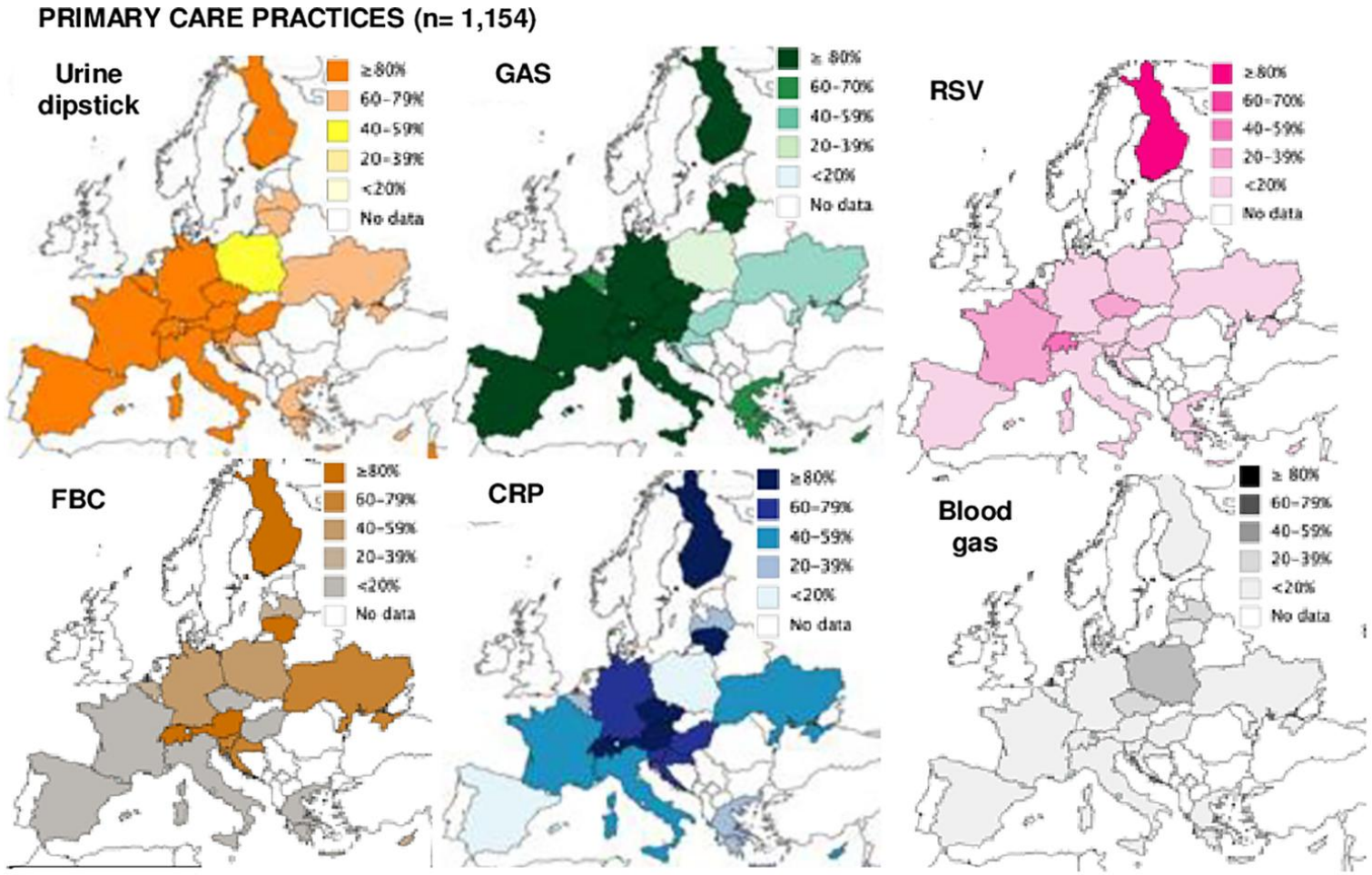
Table 3 Point-of-care tests that at least 25% of respondents in at least one country reported currently using, ranked in descending order according to total percentage of general practitioners that reported using the tests

	Australia (n=298)	Belgium (n=319)	The Netherlands (n=639)	UK (n=1109)	USA (n=405)	Total (n=2770)
Urine pregnancy test	68% (203)	61% (193)	94% (603)	80% (887)	86% (350)	81% (2236)
Urine leucocytes or nitrite	NA	87% (275)	96% (611)	90% (993)	88% (355)	81% (2234)
Blood glucose	74% (221)	87% (278)	96% (616)	69% (760)	82% (334)	80% (2209)
INR	48% (144)	12% (37)	1% (6)	43% (476)	47% (189)	31% (852)
Haemoglobin	10% (29)	3% (8)	58% (371)	16% (174)	50% (202)	28% (784)
Faecal occult blood	6% (19)	18% (56)	2% (14)	13% (143)	83% (335)	20% (567)
Throat swab for group A streptococci	6% (19)	4% (12)	1% (4)	15% (164)	86% (348)	20% (547)
C reactive protein	3% (8)	3% (10)	48% (305)	15% (163)	10% (42)	19% (528)
Quantitative β-human chorionic gonadotropin	6% (18)	19% (59)	22% (138)	17% (193)	28% (112)	19% (520)
HbA1c	6% (17)	2% (6)	6% (38)	17% (183)	40% (162)	15% (406)
Nose/throat swab for influenza	7% (20)	1% (3)	0% (2)	6% (61)	60% (242)	12% (328)
Platelet count	4% (11)	0% (1)	1% (3)	15% (163)	28% (112)	10% (290)

HbA1c; glycated haemoglobin; INR, international normalised ratio; NA, not applicable.

Howick *et al., BMJ Open, 2014*
https://doi.org/10.1136/bmjopen-2014-005611

Use of POCT for management of infections - Europe / paediatrics in primary care



Dewez *et al., PLoS One, 2022*
https://doi.org/10.1371/journal.pone.0275336

GP desire for POCT – mismatch with current use

Table 2 Conditions for which respondents would like a point-of-care test to help them diagnose conditions: top 10 in each country

Australia (n=298)		Belgium (n=319)		The Netherlands (n=639)		UK (n=1109)		USA (n=405)	
Condition	Per cent (n)	Condition	Per cent (n)	Condition	Per cent (n)	Condition	Per cent (n)	Condition	Per cent (n)
Diabetes	57 (170)	PE/DVT	94 (300)	PE/DVT	106.5 (651)*	UTI	47 (521)	UTI	56 (225)
Acute cardiac disease	42 (126)	Acute cardiac disease	76 (241)	Acute cardiac disease	62.7 (383)	PE/DVT	43 (478)	Strep throat	54 (218)
UTI	32 (95)	Heart failure	24 (75)	Chest infection/ cough/LRTI	54.7 (334)	Diabetes	35 (385)	Diabetes	42 (169)
Pregnancy	26 (79)	Chest infection/ cough/LRTI	24 (75)	UTI	26.0 (159)	Acute cardiac disease	25 (282)	Influenza	40 (162)
Anaemia	18 (53)	Infections	23 (74)	Heart failure	22.9 (140)	INR/anticoagulation	18 (199)	Pregnancy	25 (103)
Chronic and acute renal conditions (excluding UTI)	15 (45)	UTI	19 (61)	Anaemia	20.0 (122)	Pregnancy	16 (178)	Infectious mono	14 (56)
INR/anticoagulation	17 (51)	Acute and chronic renal impairment	12 (39)	Diabetes	14.7 (90)	Anaemia	15 (162)	Anaemia	13 (52)
PE/DVT	13 (40)	Diabetes	12 (37)	Infections	13.1 (80)	Heart failure	11 (124)	STDs	7 (27)
Heart failure	12 (37)	Anaemia	8 (24)	Appendicitis	10.8 (66)	COPD/asthma	10 (116)	INR	7 (27)
COPD/asthma	12 (35)	STDs	7 (21)	STDs	9.0 (55)	Chest infection/ cough/LRTI	9 (102)	Acute cardiac disease	6 (23)

*>100% Since we combined PE and DVT. This is because some respondents in the Netherlands listed *both* PE and PE/DVT. In other countries we faced similar problems. Since it was impossible to split PE from DVT when respondents listed PE/DVT as a single condition, we lumped them together.
COPD, chronic obstructive pulmonary disease; DVT, deep vein thrombosis; INR, international normalised ratio; LRTI, lower respiratory tract infection; PE, pulmonary embolism; STD, sexually transmitted disease; UTI, urinary tract infection.

Howick *et al., BMJ Open, 2014*
https://doi.org/10.1136/bmjopen-2014-005611

Challenges (considerations!) and solutions

Analysis

Implementing in-vitro diagnostic point-of-care tests in community health care:

how can we make this work?

Philip J Turner, Umasha Ukwatte, Ian Smith, Tim James, Paul Stephenson, Sarah Tonkin-Crine, Margaret Głogowska and Gail N Hayward

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Turner *et al., BJGP, 2025*
https://doi.org/10.3399/bjgp25X741153

Critical domains for implementation in community care

- Clinical need
- Evidence of clinical performance
- Maintenance of quality
  - Operator competence
  - Quality control and EQA
- Practicalities
  - Management of consumables
  - Environmental
  - Footprint, weight and capability
  - Biosafety
- Data Capture and integration
- Funding

Turner *et al., BJGP, 2025*
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Evidence of performance and impact

Verbakel *et al., BJGP, 2017*
https://doi.org/10.3399/bjgp25X741153

Clinical performance evidence

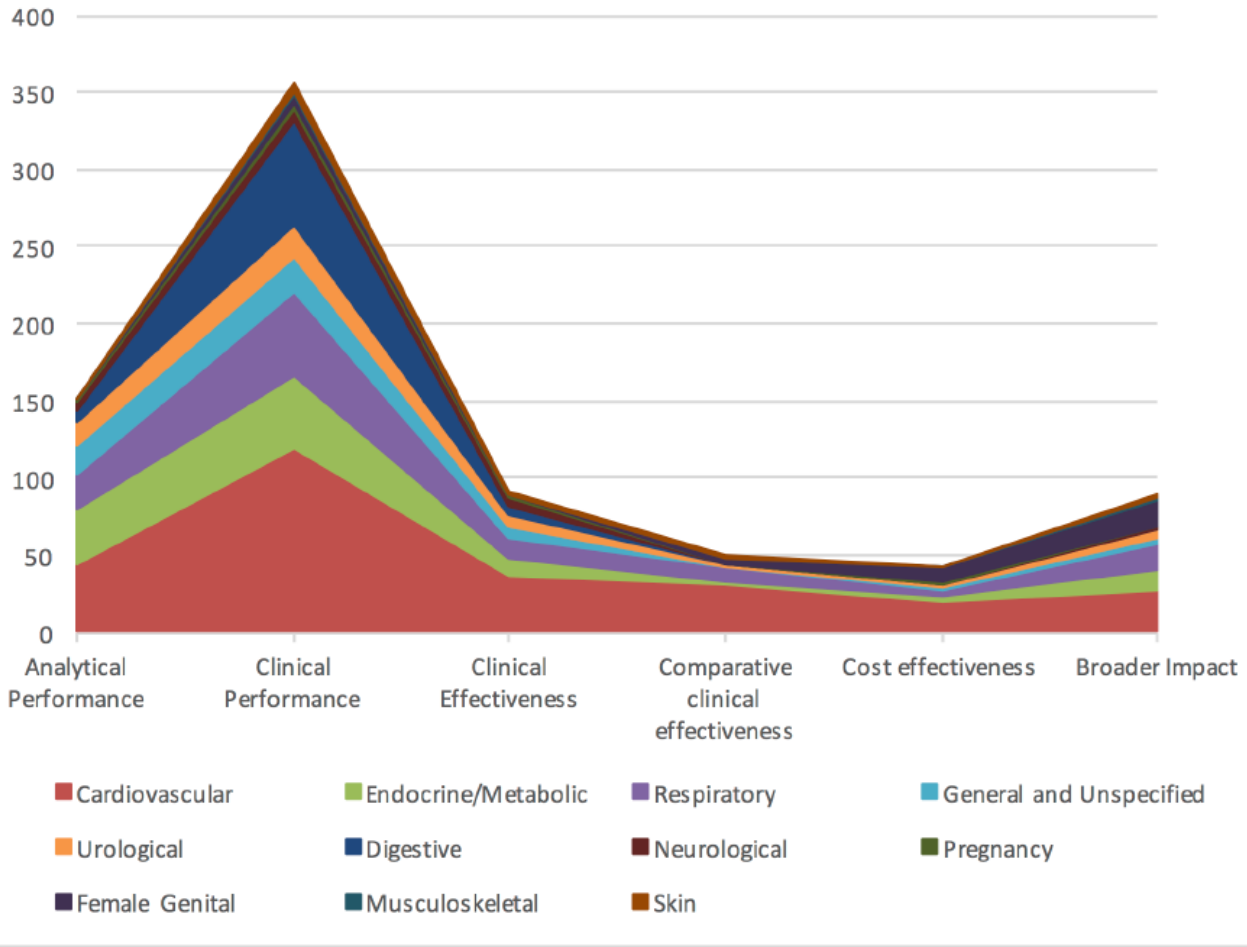


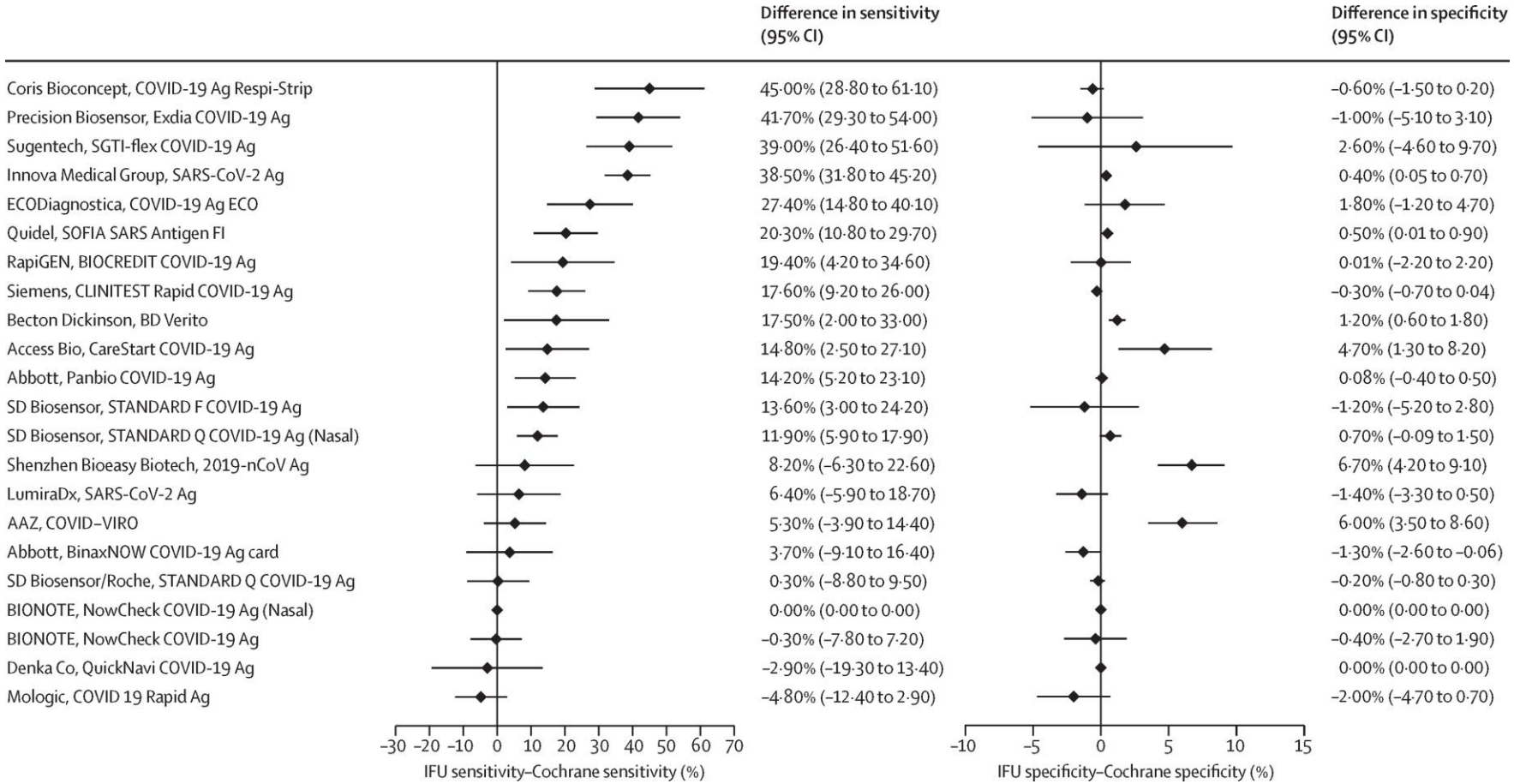
Figure 3 Test evaluation component by disease area in absolute number (n) of studies.

Verbakel *et al., BJGP, 2017*
https://doi.org/10.3399/bjgp25X741153

Challenge – Lack of relevant evidence

- Approved documentation of IVDs easy point of call for commissioners of healthcare / clinicians
- Test performance data dominated by conformity assessment reports
- Historic lack of requirement for contextualised evidence as an element of conformity assessment
- General clinical scepticism related to the performance of new tests, has the potential to lead to excessive resource utilisation and repetition
- No good central repository for validation / verification evidence that could be accessed by potential users

Why is context relevant evidence important?



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Bigio et al., Lancet Microbe, 2023
https://doi.org/10.1016/S2666-5247(23)00222-7

Potential regulatory-driven solution? – point-of-care

CE IVD-R Requirements Regarding Performance, Design and Manufacture

"The characteristics and performances of the device shall be specifically checked in the event that they may be affected when the device is used for the intended use under normal conditions:

(a) For devices for self-testing, performances obtained by laypersons;

(b) For devices for near-patient testing, performances obtained in relevant environments (for example, patient home, emergency units, ambulances)."

[CE IVD-R Annex I, Chapter II, 9.4]

Potential evidence repository solution? – SKUP

- Scandinavian evaluation of laboratory equipment for point of care testing (SKUP)
- Collaboration between Denmark, Sweden and Norway
- Standardised evaluation methodology and central repository for reports
- Aimed to potentially reduce repetition and improve transparency
- POCT achieving pre-defined performance criteria can potentially be implemented across the three countries

https://www.skup.org/

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Turner *et al., BJGP, 2025*
https://doi.org/10.3399/bjgp25X741153

Maintenance of quality

- Operator competence
  - Isolated implementation of POCT and reliance on manufacturer training
  - Central ‘expert’ governance / supervision challenging in devolved community settings like primary care
  - Lack of integration with middleware solutions which might facilitate identification of emerging problems and corrective action
  - Skills maintenance challenging where tests used infrequently
  - Contrast with countries with established POCT infrastructure and embedded BMS support
- Quality control and EQA
  - QC and EQA often unfamiliar concepts in community due to limited use of POCT
  - Seen as an additional administrative burden

Practicalities

- Management of consumables
  - Refrigeration
  - Stock control
  - Infrequently used tests, QC materials and wastage
- Environmental
  - Operating temperature / humidity and contexts of use
  - Hirst et al., 2021. HbA1c testing in South Africa
  - Nicholson et al., SARS-CoV-2 testing in the community

https://doi.org/10.1136/bmjopen-2020-045511
https://doi.org/10.1371/journal.pone.0288612

Practicalities

- Footprint (and accessibility!), weight and capability
  - Limited space in many community-based clinics to accommodate equipment
  - OOH study* suggested that small ‘barriers’ can have big consequences for use
  - General indication from primary care that ‘platform’ technologies preferable to multiple devices
- Biosafety
  - Community healthcare not necessarily equipped to mitigate the additive risk of testing for infectious diseases

Dixon et al., Antibiotics, 2022
https://doi.org/10.3390/antibiotics11081008

Quality / Practicalities – potential solution?

- Extension of pathology service reach as potential providers of POCT
- Examples at OUH, Frimley and others
- Includes
  - Provision of training
  - Governance
  - Stock control
  - Data management
  - Administration of EQA processes
- **Critical** – allows community clinical end-users to focus on care delivery

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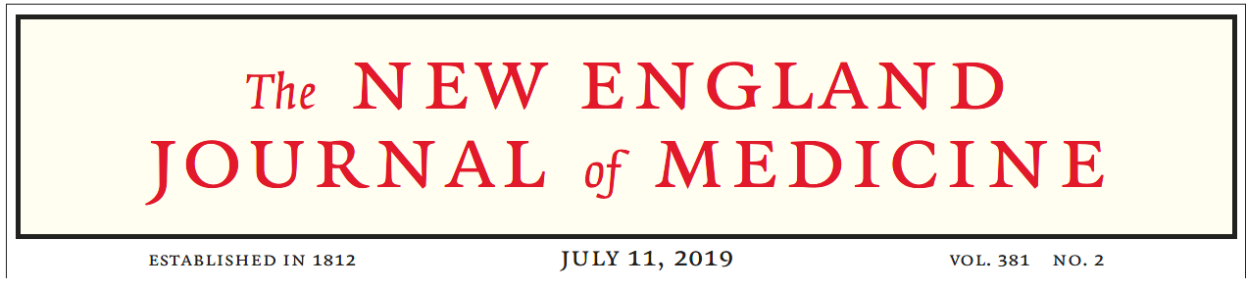
Funding



The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JULY 11, 2019 VOL. 381 NO. 2

C-Reactive Protein Testing to Guide Antibiotic Prescribing for COPD Exacerbations

Christopher C. Butler, F.Med.Sci., David Gillespie, Ph.D., Patrick White, M.D., Janine Bates, M.Phil., Rachel Lowe, Ph.D., Emma Thomas-Jones, Ph.D., Mandy Wootton, Ph.D., Kerenza Hood, Ph.D., Rhiannon Phillips, Ph.D., Hasse Melbye, Ph.D., Carl Llor, Ph.D., Jochen W.L. Cals, M.D., Ph.D., Gurudutt Naik, M.B., M.S., M.P.H., Nigel Kirby, M.A., Micaela Gal, D.Phil., Evgenia Riga, M.Sc., and Nick A. Francis, Ph.D.

- Randomised controlled trial of clinical and cost effectiveness
- Demonstrated meaningful reduction of antibiotic prescribing without harming patients
- Was popular with GPs, but has struggled for traction
- BUT – informed the All Wales COPD management and prescribing guideline

Butler *et al., NEJM, 2019*
https://doi.org/10.1056/NEJMoa1803185

In conclusion

Potential benefits, but many challenges for community implementation of POCT

Potential benefits, but many challenges for community implementation of POCT

Pathology service support will be **essential** to achieve safe and sustainable implementation of appropriate POCT in the community

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Thank you

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