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The Critical Role of Rapid CYP2C19 Pharmacogenetic Testing In Enabling NHS Reform Ambitions

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Problem & consequence

The NHS faces a critical challenge; reduce waiting lists, save money and improve patient outcomes.

"Genotype-guided prescription"

*"the **right** drug at the **right** dose for the **right** patient at the **right** time"*

- ***98%** of individuals have at least one actionable PGx DNA variant for a common medication*
- *Leading to inneffictive medicines (poor/no response) and Adverse Drug Reactions (16.5% of hospital admissions = £2.2Bn)*

- *NHS spend of **£20Bn** pa on **prescription medications***
- *Analgesics (£438M), Antidepressants (£224M), Antiplatelets (£66M).*

- *DNA analysis from patient samples for Pharmacogenetic testing typically processed in central diagnostic laboratories (e.g. GLHs)*

- *Takes **several days to weeks** for clinician to have a result enabling actionable prescription changes.*

- ***NOT VIABLE FOR EMERGENCY HEALTHCARE PARADIGMS WHERE TIME IS CRITICAL.***

"Prevention" is central to Government 10 year NHS ambitions:

HOW TO IMPLEMENT?

Stroke – National Priority

Leading cause of disability & **4th largest cause of death** in UK.

100,000 strokes pa in UK, **1 every 5 mins**, with 50% left with disability.

Stroke costs the UK economy **£26 billion pa**, (£3.4bn NHS, £5.2bn social care, £15.8bn informal)

By 2035, number of people having a stroke will increase by almost half, and the number of stroke survivors by a third.

Cost burden forecast to rise to **£91bn** by 2035

Highest mortality & incidence in those with highest deprivation and ethnic minority groups.

Rapid access care pathways, with effective preventative therapies within 24 – 48hrs are crucial.

Stroke – National Priority

NICE & Royal College of Physicians guidelines state prescription of antiplatelet Clopidogrel in IS/TIA, **within 24 hours**.

Clopidogrel is **ineffective in >25%** of individuals (up to 56%), due to DNA variants in the CYP2C19 gene.

Ineffective antiplatelet at vulnerable time. Higher risk of stroke recurrence & in certain ethnic groups. More hospital readmissions, longer stays, higher costs.

Testing for known DNA variants in the CYP2C19 gene can ensure the right patients receive clopidogrel.

NHS Genomic laboratories cannot identify these known DNA variants in the most optimal clinical timeframe.

Solution - Intervention

- **Genedrive CE-IVD CYP2C19 ID Kit.**
  - ***Maximal ethnic inclusivity*** *of DNA variants, in* ***70 mins*** *from buccal cheek swab.* ***Near-patient testing.***
  - ***Outperforms laboratory testing*** *platform.*

Rapid Pharmacogenetics

Stroke Patient Admitted

Clinician to administer treatment within 24hrs

Metaboliser status not known

>25% of patients do not metabolise = higher risk

With Genedrive® System Implemented

Normal/Rapid/Ultrarapid Metaboliser status identified

Clopidogrel

Intermediate/Poor Metaboliser status identified

25-56%

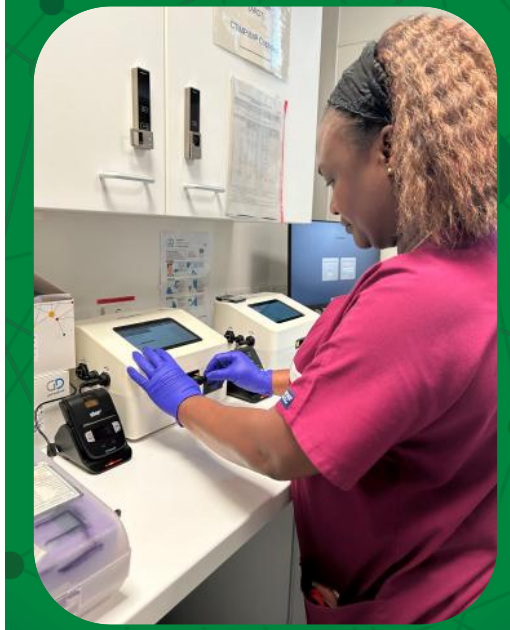
Consider alternative antiplatelet

Transforming patient outcomes through rapid pharmacogenetic testing

CYP2C19

Development and Validation of a Rapid Point-of-Care *CYP2C19* Genotyping Platform

jmdjournal.org



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Solution – Current status

NICE

National Institute for Health and Care Excellence

- **Recommended by NICE for use in the NHS**
  - *Dominant health economics*
  - *Available via NHS Dynamic Purchasing System*
  - *Cyberessentials, DTAC & DPST compliant*

NHS Northern Care Alliance NHS Foundation Trust

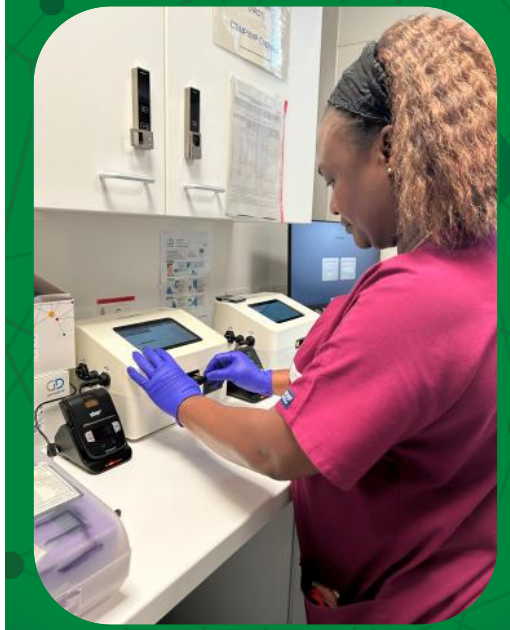
- **Implemented into routine clinical practice**
  - *Salford Hyperacute Stroke Centre (largest in NHSE)*
  - *Peterborough City Hospital stroke centre*

NHSE-led pilot (logistics of implementation)

	All 3 lab sites (Dec 24-Apr 25)	POCT site (March-Apr 25)
Patient status when result received	197/225 discharged	On ward

Awaiting NHSE final report publication and implementation plan

CYP2C19



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National Impact

Significantly better patient outcomes & substantial annual productivity gains.

- Estimated **£160 million** of value to NHSE each year.

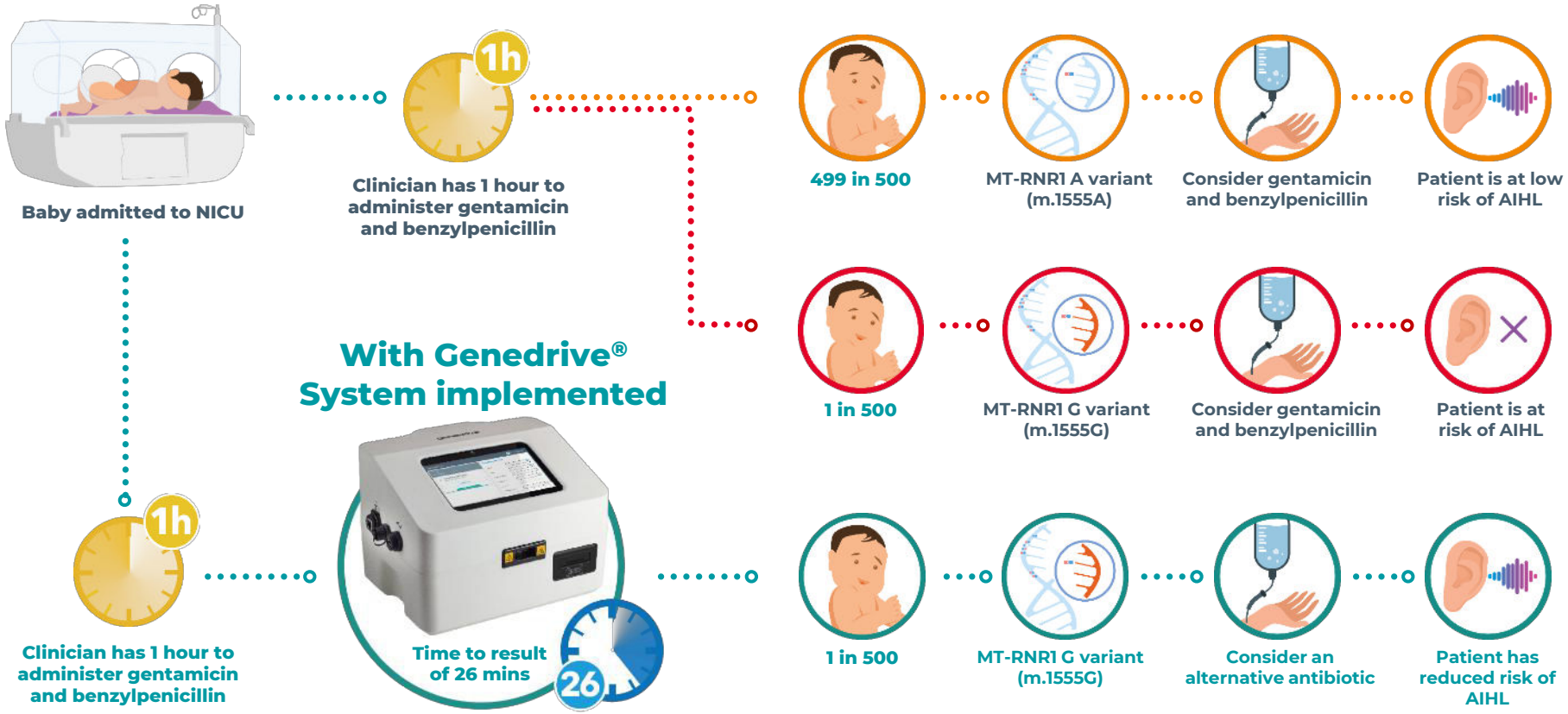
Rapid genetic testing (p.a):

- 2,855 recurrent stroke admissions prevented.
- 231,000 HCP hours released.
- **62,505 bed days released.**

IQVIA

Antibiotic Induced hearing Loss (AIHL)

- Further example of interventional pharmacogenetic testing driving significant patient benefits & financial savings for healthcare systems



Lifelong hearing loss could be avoided in >200 NICU babies / year in UK
In use in 14 hospitals across UK. Scotland implementing nationally.

Summary & more information..

Demonstrating real world patient benefit and prevention in line with the NHS Ten-Year Plan

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