Laboratory Anywhere - Transformation of Diagnostic Delivery

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• Consultant Clinical Biochemist,
• Laboratory Director, Clinical Biochemistry
• Associate Divisional Medical Director of Diagnostics
• Diagnostics needs to be delivered wherever it is needed:
  • Central Diagnostic and Specialist Hub
    – Already delivered
  • Rapid response labs
    – Already delivered
  • Point of care diagnostics
    – Partially delivered
  • “Lab in a Box” in the community and clinics
    – Technology has arrived
  • Hospital and Laboratory at home
    – Technology arriving- passive and active monitoring
## NHS Reference Costs for Direct Access Pathology

### Table 1. Pathology Reference costs: Actual NHS data*

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### Table 2. Pathology Reference costs: 2009 costs with CPI adjustment to 2015 prices, compared with 2015 reference costs **

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*NHS Reference Costs

Go to: National Schedule, Index, Chose DAPS

**CPI Adjustment:
http://www.bankofengland.co.uk/education/Pages/resources/inflationtools/calculator/index1.aspx
Laboratory Anywhere
Transformation of Pathology Delivery

www.england.nhs.uk
Publications gateway number: 03172

“Designing the NHS around our patients”
Value-orientated Pathology strategy

Patient pathway redesign

- In England less than 1% of commissioner cost is on direct access pathology

- Reducing pathology spend by 20% makes little difference

- If more is spent on pathway-focussed pathology then could we save 20% of the pathway?
“Designing the NHS around our patients”
Using Diagnostics to support Personalised Patient Pathways

• Over 80% of all clinical decisions require laboratory tests
• Strategic use of diagnostics can help redesign patient pathways and meet the National and Local Agendas
  – New tests
  – New technologies
  – New localities
  – New delivery models
  – Manpower review
  – Patient involvement in pathway management
  – Disease prevention
• Diagnostics needs to be delivered wherever it is needed:
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  • Hospital and Laboratory at home
    – Technology arriving- passive and active monitoring
Laboratory Anywhere: **Taking the laboratory to the patient**

- Patient-focused Pathology
- Take the laboratory to where it adds most value to the patient journey
  - Lab in a bag
  - Lab in a box
Laboratory Anywhere: Taking the laboratory to the patient

- Patient-focused Pathology
  - Lab in a bag
  - Lab in a box

- Extended POCT in now emerging in multiple locations:
  - Outreach teams
  - Locality labs/Urgent care centers
  - Rapid access Clinics
  - Care Homes
  - Ambulances
  - Hard to access patients
  - GP surgeries
  - Pharmacies
  - Home
Lab in a Bag: Outreach teams

Diagnostic devices for decision making:
- U&E, glucose, ketone, CRP, lactate, gases, INR

Critical Care Outreach Team:
- AKI and Sepsis outreach team
- Piloted at RPH with Alere Epoc-BGEM:
  - Na⁺, K⁺, Cl⁻, creatinine, eGFR
  - pH, pCO₂, pO₂
  - Lactate
  - Ca²⁺
  - Glucose
  - Hct
Lab in a Box: **Locality Hospitals, Urgent Care Centers**, 

- Emergence of Locality Hubs requiring diagnostics
Lab in a Box: Frailty units

- Emergence of Frailty units in the community requiring diagnostics
- Plan to put the Epoc-BGEM in the Longridge Frailty unit
Lab in a Box: **Rapid access clinics**

**Renal clinics:**
- Rapid Renal Out Patients
- Dialysis units
  - Albumin
  - Alk Phos
  - ALT
  - AST
  - Total protein
  - Ca$^{2+}$
  - Creatinine
  - Urea
  - Amylase
  - CRP
  - Glucose
  - Uric acid

**Rheumatology Clinics**
- Titrating therapy with CRP
Total time taken to complete the pathway is approximately 40 minutes.

Time & sequence of patient care pathway may vary depending on patient’s needs.
Lab in a Box: **Care Homes**

The Bolton Care Home Pilot

- 32 care homes, 1500 patients
- Nurses from Bolton Hospital attend the Care Homes
- Patients are assessed
- Nurses will use Lab in a Bag Technology to assist in decision making
Lab in a Bag: Ambulances

- Frailty and Falls are common reasons for ambulance call outs
- Essex and Herts Air Ambulance now using INR meters as apart of their rapid assessment of the “fallen” patient
Lab in a Bag: Lab in a Van (why not?)

- Phlebotomy
- Health checks
- INR
Lab in a Box: **GP surgeries**

**Diagnostic devices for decision making:**

POCT devices already present in most GP surgeries
- Urinalysis
- Glucose
- INR

The technology and guidance is rapidly evolving
- NICE CG191: pneumonia in adults; Diagnosis and management 2014
  - antimicrobial stewardship in Primary Care
  - presenting with symptoms of lower respiratory tract infection in primary care
**Antimicrobial stewardship in Primary Care:**

- Do not routinely offer antibiotic therapy if CRP < 20 mg/L.
- Consider a delayed antibiotic prescription if CRP is between 20 - 100 mg/L.
- Offer antibiotic therapy if CRP is > 100 mg/L.

**Several sites already doing it**

- Wales
- Preston Pilot: “if it works we want 66 devices next winter”
Real-time, portable genome sequencing for Ebola surveillance
Quick J, Loman NJ, Duraffour S
Nature 2016:530;228-232
Lab in a box: Hard to access patients
Lab in a box: Hard to access patients

High quality health and care now and for future generations

Improve health
1. Improving the quality of care and access to cancer treatment
2. Upgrading the quality of care and access to mental health and dementia services
3. Transforming care for people with learning disabilities
4. Tackling obesity and preventing diabetes

Redesign care
5. Redesigning urgent and emergency care services
6. Strengthening primary care services
7. Timely access to high quality elective care
8. Ensuring high quality and affordable specialised care

Whole system change for future clinical and financial sustainability
9. Enabling whole system change
   Delivering value and financial sustainability through a step-change in efficiency

Foundations for improvement
10. Harnessing the information revolution
    Developing capability and infrastructure for transformational change
    Developing leading edge science and innovation
    Supporting patient and public participation
Mental health: Compared to the general population, the life expectancy of people with severe mental illness is reduced by around 15-20 years, with:

- Three-times increased risk of premature death
- About 75% of deaths caused by physical disorders
- Cardiovascular disease is the single biggest and potentially preventable cause of premature mortality, more common than suicide
- Diabetes is 2-3 times more common (almost entirely from type 2 diabetes)
- Belgian study found that 37% of people with schizophrenia by the age of 38, were biochemically at high risk of developing diabetes
Positive Cardiometabolic Health Resource

An intervention framework for people experiencing psychosis and schizophrenia

### Smoking
- Current smoker
- Poor diet
- AND/OR
- Sedentary lifestyle

### Lifestyle and Life Skills
- BMI ≥ 25 kg/m²
  - (≥ 23 kg/m² if South Asian or Chinese)
- AND/OR
  - Weight gain > 5 kg over 3 month period

### Body Mass Index (BMI) Weight
- BMI ≥ 25 kg/m²
- >140 mm Hg systolic
- AND/OR
- >90 mm Hg diastolic

### Blood Pressure
- HbA1C or Glucose threshold:
  - HbA1C ≥ 42 mmol/mol (6.0%)
  - AND/OR
  - FPG ≥ 5.5 mmol/l
  - OR
  - RPG ≥ 11.1 mmol/l

### Glucose Regulation
- Total chol/HDL ratio to detect high (>10%) risk of CVD based on QRISK-2 Tool
  - http://qrisk.org/
  - Note: CVD risk scores can underestimate risk in those with psychosis

### Blood Lipids

### Medication review and lifestyle advice to include diet and physical activity

**NB** Family history of diabetes and/or premature heart disease heightens cardiometabolic risk.

Refer for investigation, diagnosis and treatment by appropriate clinician if necessary.

### Interventions

**Brief intervention**
- Combined NRT and/or varenicline
- Individual/group behavioral support or specialist support if high dependency
- Referral to Smoking Cessation service

**Follow NICE guidelines for obesity**
- http://www.nice.org.uk/CG43

**Follow NICE hypertension guidelines**
- http://publications.nice.org.uk/hypertension-cg127
  - Consider anti-hypertensive therapy
  - Limit salt intake in diet

**At High Risk of Diabetes**
- HbA1c ≥ 42 mmol/mol (6.0% - 6.4%)
- FPG ≥ 7.0 mmol/l
- RPG ≥ 11.1 mmol/l
  - Endocrine review
  - Follow NICE diabetes guidelines
  - http://www.nice.org.uk/CG97
  - Consider lipid modification for those with CVD or Diabetes

**Diabetes**
- HbA1c ≥ 48 mmol/mol (6.5%)
  - FPG ≥ 7.0 mmol/l
  - RPG ≥ 11.1 mmol/l
  - Consider intensive structured lifestyle education programme
  - If ineffective consider metformin

**Follow NICE guidelines for lipid modification**
  - AND
  - Refer to specialist if total cholesterol >9, non-HDL chol >7.5 or TGs >20 (mmol/l)
  - AND
  - Consider lipid modification for those with CVD or Diabetes

### Target

- Stop smoking
  - Contain calorie intake
  - Daily exercise of 30 mins/day
  - BMI 18.5-24.9 kg/m²
    - (18.5-22.9 kg/m² if South Asian or Chinese)
  - <140/90 mm Hg
    - (<130/80 mm Hg for those with CVD or diabetes)
  - Prevent or delay onset of diabetes
    - HbA1c < 42 mmol/mol
      - (-6%)
    - FPG < 5.5 mmol/l
  - Primary Prevention:
    - Consider Statin treatment if ≥10% risk based on QRISK2
    - OR
    - Secondary Prevention:
      - aim to reduce non-HDL chol by 40% and review in 3 months

FPG = Fasting Plasma Glucose | RPG = Random Plasma Glucose | BMI = Body Mass Index | Total Chol = Total Cholesterol | HDL = High Density Lipoprotein | TRIG = Triglycerides
Lab in a Box: **Mental Health**

- Mental Health Patients are dying younger due to *not accessing diagnostic testing*
- NHSE Mental Health Diagnostics Group
- Pop-up Laboratories:
  - Mental Health pop-up Clinics
    - Initial screening will be at Drug Depot Clinics
    - Measuring HbA1c, Total cholesterol, HDL cholesterol
    - Preston, Salford, London
    - HEE funding for training
Lab in a Box: Learning Disabilities

- Patients with Learning Disabilities are dying younger due to not accessing diagnostic testing
- Pop-up Laboratories:
  - Pilots at Chorley 2015 and 2016: HBA1c, Total Cholesterol, HDL
Lab in a Box: Learning Disabilities

- NHSE Learning Disability Diagnostics Group
- Learning disability group
  - Commissioned University of Sunderland undertake gap analysis
  - Working with NHSE to clarify the LD Annual Health Check
  - Prepare options for LD pop-up diagnostic clinics in 2017
  - Report May 2017
Laboratory at Home: **Early detection of neutropaenic sepsis**

- Philips Minicare home monitoring service
- Self testing, results transmitted to Oncology Centre
Laboratory at home: self testing in LTC
Laboratory Anywhere: **Passive measurement**

- **Dexcom G5 Mobile CGM**
- **Smart contact lenses (Google)**
- **Abbott**

Get to know the FreeStyle Libre system.
Explore the hotspots...
Laboratory anywhere: **Wearable devices**

- **Smart Wristband**
  - Flexible sensor array
  - Wireless flexible PCB

- SEEQ Wearable Sensor
  - Easy to apply, slim-profile sensor worn discreetly under shirt or blouse.
Monitoring Anywhere: The smart home

- Smart bed, smart carpet etc
- Thermal imaging, fall detection, algorithm based behaviour sensing
Point-of-care testing could drive innovation in health systems by:

- inducing changes, such as improved patient flow within clinics.
- motivate local and international initiatives to seek ways to address existing pathways.
- elicit proactive efforts in resolving health-system bottlenecks so that the tests can be successfully used.

Is the Laboratory ready to deliver the Laboratory Anywhere Model?
Is the performance of the POCT device adequate?

- It depends on the clinical question being asked!
- Diagnosis or triaging?
- Monitoring change

Sverre Sandberg

- Performance Specifications for POCT instruments can be different from hospitals laboratories because
  - The importance of a rapid result
  - The advantage of reaching out to more people
  - The possibility of more rapid serial result

- We need to let the user know the Uncertainty of the Measurement
Laboratory anywhere: **Implications for Quality**

- Who decides whether a device is good enough?
- Direct purchase or framework purchase
  - Need for central NHS Assessment
- Quality framework
  - Barnes QA review
  - UKAS ISO 15189 and 22870
  - MHRA Guidelines
- All require Laboratory support of diagnostics wherever they are delivered
  - Integrated POCT strategy committee
- EQA for POCT
Laboratory anywhere: **Implications for Informatics**

- All results need to go back to the patient record
The Vision

- To deliver a single system which provides the infrastructure to enable full connectivity of all approved Point Of Care Testing devices across Wales in all suitable locations.

- Integration with patients’ medical records would allow tests results to be shared and viewed, regardless of where the patient received care, or where the test was undertaken.

Annette Thomas
Laboratory anywhere: **Implications for the workforce**

- The Laboratory anywhere model will require increased laboratory staff with extended skills
- Community Scientists/diagnosticists
- More testing will be performed by non-laboratorians who will require training and competency support
Laboratory anywhere:  **Implications for finances**

- The cost of point of care is coming down, but

- Silo costing:
  - Lab vs POCT

- Integrated costing
  - Cost of Pathway with POCT v Cost of Pathway without POCT

- Need to apply Health Economics to Pathology delivery models
Laboratory Anywhere: **Transformation of service delivery**

**Conclusion**

- The Laboratory Anywhere model using Lab in a Box and Lab in a Bag, can deliver diagnostics where it is needed
  - It is happening already
- Integrated IT and Governance will underpin this
- Financial and service delivery paradigm shift

- If the Laboratory ignores the new diagnostics, it will happen anyway

“Designing the NHS around our patients”
Acknowledgements

- **Preston POCT Academy**
  - Dr Natalie Hunt, Robert Bolton
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