NIHR Diagnostic Evidence Co-operative - Oxford

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General Practice— the “perfect storm” for innovation in diagnostic tests

- ‘Front door” to NHS – diagnosis, screening, referral, gatekeeping
- Multiple, repeated, more frequent lab tests
- Aging population, multimorbidity
- Chronic disease management
- Cost-containment – reducing unnecessary referrals
- Misdiagnosis… malpractice
- Little current use of IVDs
Current mismatch impedes clinical practice & innovation in primary care

Available IVDs & technical capabilities. Accuracy/ease/size/speed/range/bundling

Current clinical practice. Minimal test dissemination and adoption in primary care

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Vision: Primary care diagnostic technology centre of excellence for the NHS & UK Diagnostics Industry

- Design, test and implement methods and strategies to increase evidence for implementation of in-vitro diagnostics in primary care
- National/International leaders in primary care & diagnostics
- Innovative NHS partners in delivery and laboratory medicine
- Research strategy across 5 main themes
Partners

- Oxford Health Foundation NHS Trust
- University of Oxford Department of Primary Care Health Sciences
  - Centre for Monitoring & Diagnosis
  - Centre for Evidence Based Medicine
  - Patient Experiences Research Group
  - Statistics Group
- Oxford Clinical Commissioning Group
- Oxford Radcliffe Trust Department of Laboratory Medicine & Microbiology
- Oxford Academic Health Science Networks
Theme 1: Identify new and emerging diagnostic technologies

Leads: Annette Pluddeman, Carl Heneghan, Chris Price, Matthew Thompson, Jane Wolstenholme

Aim: Identify and prioritise new diagnostic IVD technologies

• Horizon-scanning process to identify, prioritise and produce diagnostic evidence reports for IVDs
• Highlight research and implementation gaps - ‘next steps’
• 130 different tests across 30+ clinical areas (funded by NIHR programme grant)
• Dissemination – HTA, NICE, commissioners, industry, primary care
31 point of care test areas evaluated (approx 140 different diagnostic tests)

- **Point of care tests (15), e.g.**
  - Point of care CRP test for antibiotic targeting
  - Point of care D dimer test for ruling out deep vein thrombosis
  - Point of care test for HbA1c
  - Point of care test for INR
  - Point of care test for blood ketones

- **Electronic tests (11), e.g.**
  - Handheld ECG monitor for detecting atrial fibrillation
  - Handheld electronic nose for diagnosis of cancer, asthma, infection
  - Pulse oximetry
  - Handheld spirometry for diagnosis and monitoring of COP
  - Transcutaneous bilirubin measurement

- **Others**
  - Urine sample techniques in older individuals
  - Frailty screening tools
‘Rapid’ evidence reports

- Clearly defined clinical question
- What diagnostic devices are available?
  - Details
  - Potential advantages over existing technology
- Current practice, Patient group, importance
- Previous research
  - Accuracy vs. existing tests
  - Impact vs existing tests
  - Cost effectiveness
- What research still needs to be done?
- What is the suggested next step?
- Bottom line
Theme 2: Identify unmet diagnostic testing needs in primary care

Leads: Ann Van den Bruel, Jeremy Howick, Caroline Jones

Aim: needs assessment of primary care clinicians for diagnostics

• UK & International (NL, BE, Australia, USA) surveys of primary care doctors’ current use and needs for IVDs
• Expand needs assessment to other ‘front line’ clinicians
• Process for rapid needs assessment of diagnostic testing
## International survey of GP/Family Physician current use and desired use of point of care tests. Howick J, et al

<table>
<thead>
<tr>
<th>Country</th>
<th>UK</th>
<th>Netherlands</th>
<th>Belgium</th>
<th>Australia</th>
<th>USA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sampling method</td>
<td>Randomly sampled, stratified according to age, length of time in practice, specialty, and location</td>
<td>All GPs in three regionally distributed GP networks approached</td>
<td>Existing mailinglist of GP plus GP groups of the region contacted</td>
<td>GPs in SA &amp;QLD GPs (total 2933). AMA membership list with addition of data from other sources. (approximately 80% GP coverage)</td>
<td>AAFP National Research network and Doctors.net</td>
</tr>
<tr>
<td>Type of survey (electronic, paper based)</td>
<td>Electronic</td>
<td>Electronic</td>
<td>Electronic</td>
<td>Electronic and paper</td>
<td>Electronic</td>
</tr>
<tr>
<td>Number of respondents (response rate%)</td>
<td>1109 (68%)</td>
<td>639 (30%)</td>
<td>319 (not available)</td>
<td>298 (10%)</td>
<td>405 (74%)</td>
</tr>
<tr>
<td>Location of practice*</td>
<td>Rural or Semirural</td>
<td>377 (34%)</td>
<td>280 (43.8%)</td>
<td>176 (55%)</td>
<td>280 (43.8%)</td>
</tr>
<tr>
<td>Urban or Suburban</td>
<td>293 (26%)</td>
<td>359 (56.2%)</td>
<td>143 (45)</td>
<td>359 (56.2%)</td>
<td>303 (75%)</td>
</tr>
<tr>
<td>Kilometres to nearest hospital (average)</td>
<td>11.2km</td>
<td>8.6km</td>
<td>7.1km</td>
<td>n/a</td>
<td>7.9km</td>
</tr>
</tbody>
</table>

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Oxford Health NHS Foundation Trust

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<table>
<thead>
<tr>
<th></th>
<th>United Kingdom (n=1109)</th>
<th>Netherlands (n=639)</th>
<th>Belgium (n=319)</th>
<th>Australia (n=298)</th>
<th>United States (n=405)</th>
<th>Total (n=2770)</th>
</tr>
</thead>
<tbody>
<tr>
<td>D-dimer</td>
<td>73%(811)</td>
<td>70%(448)</td>
<td>83%(265)</td>
<td>41%(121)</td>
<td>62%(251)</td>
<td>68%(1896)</td>
</tr>
<tr>
<td>Troponin</td>
<td>69%(765)</td>
<td>65%(418)</td>
<td>85%(271)</td>
<td>43%(129)</td>
<td>59%(238)</td>
<td>66%(1821)</td>
</tr>
<tr>
<td>Chlamydia</td>
<td>65%(721)</td>
<td>60%(382)</td>
<td>67%(212)</td>
<td>49%(145)</td>
<td>66%(267)</td>
<td>62%(1727)</td>
</tr>
<tr>
<td>BNP</td>
<td>66%(734)</td>
<td>62%(398)</td>
<td>51%(164)</td>
<td>28%(82)</td>
<td>60%(244)</td>
<td>59%(1622)</td>
</tr>
<tr>
<td>CRP</td>
<td>61%(682)</td>
<td>47%(302)</td>
<td>75%(238)</td>
<td>38%(114)</td>
<td>45%(181)</td>
<td>55%(1517)</td>
</tr>
<tr>
<td>Gonorrhoea</td>
<td>58%(645)</td>
<td>51%(326)</td>
<td>56%(180)</td>
<td>34%(100)</td>
<td>65%(262)</td>
<td>55%(1513)</td>
</tr>
<tr>
<td>HbA1c</td>
<td>61%(679)</td>
<td>37%(239)</td>
<td>61%(195)</td>
<td>52%(156)</td>
<td>50%(202)</td>
<td>53%(1471)</td>
</tr>
<tr>
<td>White cell count</td>
<td>60%(661)</td>
<td>40%(256)</td>
<td>67%(212)</td>
<td>43%(127)</td>
<td>52%(212)</td>
<td>53%(1468)</td>
</tr>
<tr>
<td>Haemoglobin</td>
<td>72%(793)</td>
<td>26%(168)</td>
<td>47%(150)</td>
<td>47%(139)</td>
<td>39%(159)</td>
<td>51%(1409)</td>
</tr>
<tr>
<td>Potassium</td>
<td>61%(679)</td>
<td>33%(210)</td>
<td>47%(150)</td>
<td>33%(97)</td>
<td>57%(232)</td>
<td>49%(1368)</td>
</tr>
<tr>
<td>INR</td>
<td>47%(517)</td>
<td>54%(347)</td>
<td>77%(244)</td>
<td>21%(63)</td>
<td>43%(176)</td>
<td>49%(1347)</td>
</tr>
<tr>
<td>Nose/throat swab for influenza</td>
<td>55%(609)</td>
<td>36%(231)</td>
<td>59%(187)</td>
<td>43%(128)</td>
<td>33%(134)</td>
<td>47%(1289)</td>
</tr>
<tr>
<td>ESR</td>
<td>58%(645)</td>
<td>29%(183)</td>
<td>40%(128)</td>
<td>29%(86)</td>
<td>48%(194)</td>
<td>45%(1236)</td>
</tr>
<tr>
<td>Quantitative Beta HCG</td>
<td>53%(586)</td>
<td>23%(149)</td>
<td>56%(177)</td>
<td>40%(120)</td>
<td>46%(187)</td>
<td>44%(1219)</td>
</tr>
<tr>
<td>Creatinine</td>
<td>53%(593)</td>
<td>28%(177)</td>
<td>41%(130)</td>
<td>34%(102)</td>
<td>53%(214)</td>
<td>44%(1216)</td>
</tr>
<tr>
<td>TSH</td>
<td>53%(586)</td>
<td>27%(171)</td>
<td>33%(105)</td>
<td>32%(95)</td>
<td>62%(253)</td>
<td>44%(1210)</td>
</tr>
<tr>
<td>Throat swab Group A Streptococci</td>
<td>53%(588)</td>
<td>33%(208)</td>
<td>60%(190)</td>
<td>35%(103)</td>
<td>11%(45)</td>
<td>41%(1134)</td>
</tr>
<tr>
<td>Uric Acid</td>
<td>50%(549)</td>
<td>26%(167)</td>
<td>30%(94)</td>
<td>28%(82)</td>
<td>51%(205)</td>
<td>40%(1097)</td>
</tr>
<tr>
<td>Sodium</td>
<td>51%(571)</td>
<td>19%(122)</td>
<td>21%(66)</td>
<td>30%(88)</td>
<td>42%(172)</td>
<td>37%(1019)</td>
</tr>
</tbody>
</table>
Theme 3: Integrating IVDs in primary care with laboratory services

Leads: Jonathan Kay, Chris Price, Dan Lasserson

Aim: determine barriers and facilitators to point of care test implementation

- Identify new methods and technologies to seamlessly link POCT in primary care with labs/medical records, within regulatory and EQA frameworks
- Use Abingdon community hospital Emergency Medical Unit as exemplar
Theme 4: Patient, carer & professional attitudes to implementing IVDs in primary care

Leads: Caroline Jones, Louise Locock

Aim: Understand impact and interaction of IVDs on patients, carers and professionals

- Qualitative studies of IVD acceptability and feasibility
  - CRP test children in out of hours setting
  - BNP/CKD adults
- Secondary analysis of existing Health Experience Research Group patient interviews
- Develop rapid qualitative assessment service for industry
Theme 5: Improved methods for deriving and translating evidence for diagnostic tests

Leads: Dr Rafael Perera, Richard Stevens, Beth Shinkins, Ann Van den Bruel

Aim: develop new methods for translate evidence from IVDs from secondary to primary care

- Where do diagnostic technologies ‘fall down’ along the evidence pathway, and how can these be predicted and avoided?
- How can existing diagnostic accuracy evidence from secondary care settings inform primary care
- Barriers to calibrating test characteristics across settings.
- Further examining patient centered outcomes of diagnostic tests
Joint DEC-Industry applications

- Experience with Industry-funded research across number clinical areas (e.g., heart failure, POCT, infection) and settings (e.g., primary care, out of hours, hospital)
- Large portfolio of NIHR/HTA/BRC-funded research
- UK Diagnostics Forums (2011, 2013, 2014)
Joint DEC-Industry applications

- EU 2020 grant applications March 2014
  - Large multinational
  - SME
- NIHR Programme grant
  - SME
- Joint applications in process:
  - SME
  - 2 multinationals
  - Exploring UK, European, NIH funding
Thank you

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<table>
<thead>
<tr>
<th>Test</th>
<th>United Kingdom (n=1109)</th>
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<th>Total (n=2770)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urine pregnancy test</td>
<td>80%(887)</td>
<td>94%(603)</td>
<td>61%(193)</td>
<td>68%(203)</td>
<td>86%(350)</td>
<td>81%(2236)</td>
</tr>
<tr>
<td>Urine leucocytes or nitrite</td>
<td>90%(993)</td>
<td>96%(611)</td>
<td>87%(275)</td>
<td>88%(355)</td>
<td>81%(2234)</td>
<td>81%(2234)</td>
</tr>
<tr>
<td>Blood glucose</td>
<td>69%(760)</td>
<td>96%(616)</td>
<td>87%(278)</td>
<td>74%(221)</td>
<td>82%(334)</td>
<td>80%(2209)</td>
</tr>
<tr>
<td>INR</td>
<td>43%(476)</td>
<td>1%(6)</td>
<td>12%(37)</td>
<td>48%(144)</td>
<td>47%(189)</td>
<td>31%(852)</td>
</tr>
<tr>
<td>Haemoglobin</td>
<td>16%(174)</td>
<td>58%(371)</td>
<td>3%(8)</td>
<td>10%(29)</td>
<td>50%(202)</td>
<td>28%(784)</td>
</tr>
<tr>
<td>Faecal occult blood</td>
<td>13%(143)</td>
<td>2%(14)</td>
<td>18%(56)</td>
<td>6%(19)</td>
<td>83%(335)</td>
<td>20%(567)</td>
</tr>
<tr>
<td>Throat swab for Group A Streptococci</td>
<td>15%(164)</td>
<td>1%(4)</td>
<td>4%(12)</td>
<td>6%(19)</td>
<td>86%(348)</td>
<td>20%(547)</td>
</tr>
<tr>
<td>CRP (C-reactive protein)</td>
<td>15%(163)</td>
<td>48%(305)</td>
<td>3%(10)</td>
<td>3%(8)</td>
<td>10%(42)</td>
<td>19%(528)</td>
</tr>
<tr>
<td>HbA1c</td>
<td>17%(183)</td>
<td>6%(38)</td>
<td>2%(6)</td>
<td>6%(17)</td>
<td>40%(162)</td>
<td>15%(406)</td>
</tr>
<tr>
<td>Nose/throat swab for influenza</td>
<td>6%(61)</td>
<td>0%(2)</td>
<td>1%(3)</td>
<td>7%(20)</td>
<td>60%(242)</td>
<td>12%(328)</td>
</tr>
</tbody>
</table>