Where is POCT Going? Challenges for Governance and Performance

Annette Thomas

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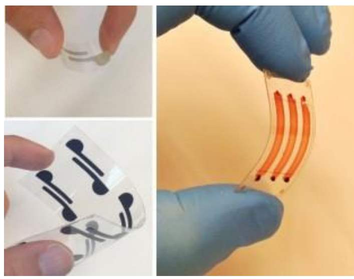
Rapid advances in biosensor technology - the smartphone

Stanford University School of Medicine (Bio-Acoustic MEMS in Medicine Labs) developed assays for the simple and rapid detection of HIV-1, various bacteria, and CD4+ T lymphocytes



sensors MDPI

Article

A Smartphone-Based Automatic Measurement Method for Colorimetric pH Detection Using a Color Adaptation Algorithm

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RESEARCH ARTICLE

A lab-on-phone instrument with varifocal microscope via a liquid-actuated aspheric lens (LAL)

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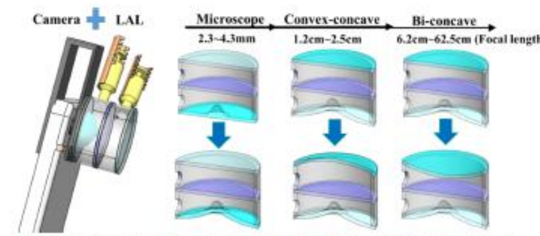

Fig 3. The structure and working mechanism of proposed LAL. Three distinctively different modes can be operated as microscope, convex-concave and bi-concave modes, respectively. The proposed LAL can be easily mounted on a smart phone via a 3d printed fixture as indicated. In the microscope mode, the tunable shapes of APLMC vary with injected volume at the bottom chamber (tunable range is experimentally measured 2.3~4.3 mm). For the operations of convex-concave mode and bi-concave mode, the tunable range can be achieved as 1.2~2.5cm (macro mode) and 6.2~62.5cm (macro mode) respectively.

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All-printed highly sensitive 2D MoS_2 based multi-reagent immunosensor for smartphone based point-of-care diagnosis

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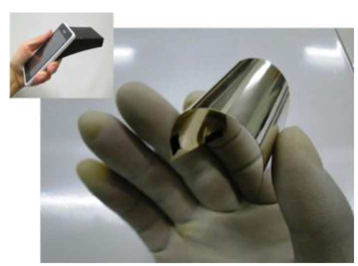
Memoon Sajid[1], Ahmed Osman[2,3], Ghayas Uddin Siddiqui[1], Hyun Bum Kim[1], Soo Wan Kim[1], Jeong Bum Ko[1], Yoon Kyu Lim[4] & Kyung Hyun Choi[1]



Large number of applications on infectious disease

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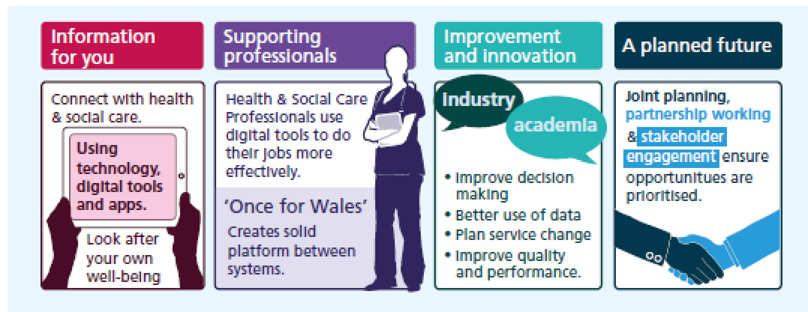
The Drivers…digital health and social care



Routinely use digital apps, wearable devices and other online resources to be well-informed and active participants in their care, able to make informed decisions and lifestyle choices to maintain their well-being.

Connect online with health and care services in the same way they do with other aspects of their life.

Use digitally-enabled services routinely to monitor long-term conditions and daily tasks to support independent living for those individuals and families.

The Drivers…digital health and social care

- Decreasing costs of sensors
- Miniaturization of physiological sensors
- Integration of sensors into consumer-end devices and accessories
- Rising share of ageing population
- Increasing incidences of chronic and lifestyle diseases
- Increased health and fitness awareness
- Rise in home and remote patient monitoring
- Reduced digital health costs
- Accountable care organizations and reimbursements
- Increasing mobile and smartphone penetration
- Increasing patient/physician acceptance
- Entry of big players such as Apple, Google, Microsoft and Amazon

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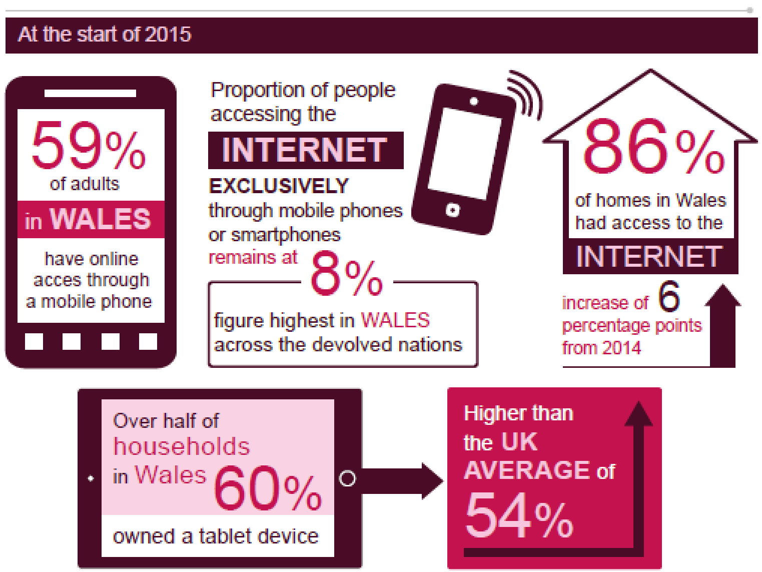
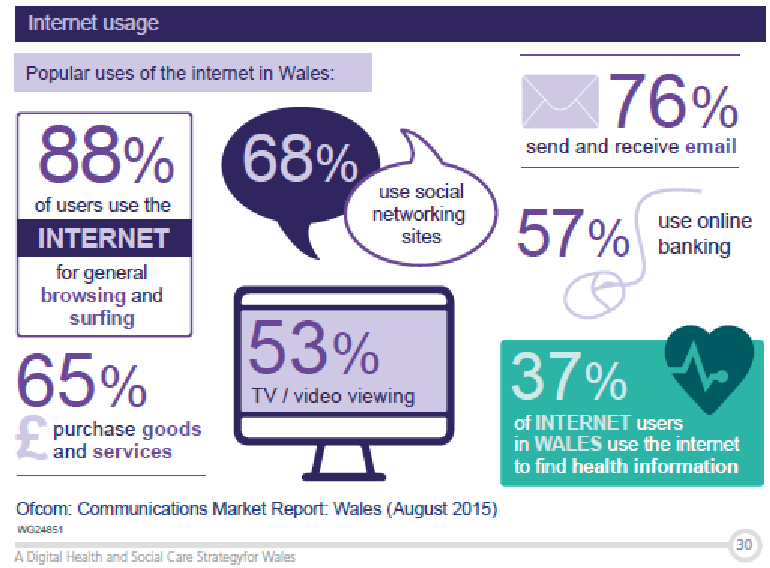
The digital revolution





- 170,000 mHealth Apps available in Apple and Google stores.
- 40% of these apps have fewer than 5,000 downloads.
- The average lifecycle of an app is 9 weeks.
- 10% of mHealth apps can connect to a device or sensor that provides physical function data.

- No NHS Wales standards/kitemarking currently exists for apps.
- NHS Choices Health Apps library recommended apps which sold data to third parties

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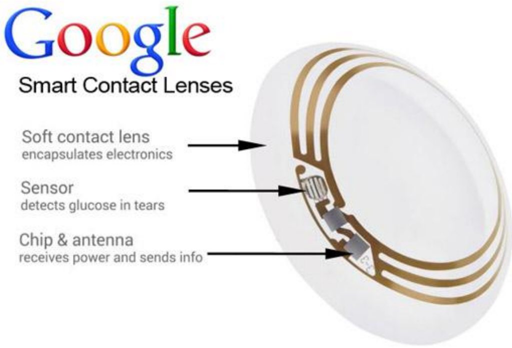
Diagnostics Anywhere – passive measurement



CGM funding available on the NHS UK

Flash glucose meter

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Challenges – implications for Quality

Is the performance of the POCT device adequate?

Who decides whether a device is good enough?

Should POCT be the same quality as laboratory tests?

- No performance specification in ISO 15189/22870
- FDA/ CE marking – is that good enough?

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Challenges – implications for Quality

- Define what is adequate? – Quality compromise
- Specification should be designed to provide performance that best meets the needs of the service.
- It will depends on clinical utility of test - what it is being used for.
- And how the service is being provided – how it is being used
- TAT can be more important e.g. HIV results / high risk population.
- Greater patient engagement– remote areas / at risk population.
- Greater patient compliance e.g. ownership of chronic disease management

Analytical Performance specification related to test utilization

Diagnosis

Q. Has the patient got disease XXX ?

Is the result significantly differe

If global "cut off" used – trueness (bias) becomes important

Monitoring

Q. Is the result significantly differen

Variation (imprecision) becomes important

Is the patient condition better or worse?

Should I change patient management ?

Population Screening

Quick and easy may override need for quality

Q. Is this subject at risk of XXX and will they need further investigation?

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Analytical performance specification of Test related to disease process

- Specification should be designed to provide performance assessment that best meets the needs of the service.
- What service is being provided?
  - Diagnosis
  - Triage
  - Monitoring – chronic disease
  - Screening - HealthChecks

Performance specification may be different for the same analyte used in different settings

e.g. Cholesterol

Total Error ± 8%

18%

Challenges – IQC & EQA

- How to IQC & EQA for implanted devices?
- Matrix effects - measurand in whole blood may not be stable so how do we undertake EQA?
- How do we assess the complete process? – for pre term markers the procedure involves obtaining a swab of cervical secretion and eluting in buffer – EQA of analytical process but not pre-analytical stage?

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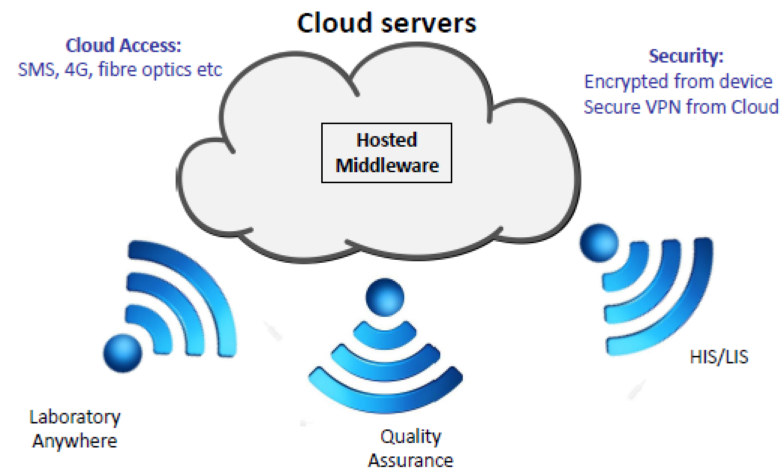
Challenges - Information Governance

- IG – Patient data entering the wrong hands or being lost in error. Need robust data security. Privacy and security concerns
- Lack of clarity in health communication protocols and standards
- Interoperability issues with TECS

Laboratory anywhere: Implications for Informatics

- All results need to go back to the patient record



Conclusion

- Rapid advancement in biosensor technology combined with the “digital revolution” within healthcare is driving the increase in the development and use of POCT.
- Our challenges are to ensure that the performance meets the clinical utility of the test, that governance processes are robust and that information governance is not compromised.

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