Intervention for Innovation (i4i) Working Groups Summary Report

Co-design: Development and in-vitro validation of an ultrasensitive multianalyte biosensing patch for real-time monitoring of brain injury and infection severity

Patient and Public Working Groups

Perceived benefits of the device

1. Monitoring for deterioration which was perceived to be unpredictable.
2. Hope that future use of the device/patch has the potential to replace repeated MRI scans and/or lumbar punctures.
3. Device applicability in low-to-middle income countries (LMICs) and the NHS due to low cost.
4. Patients perceived the patch as less invasive than blood tests (there was an agreement that patients would be happy to accept occasional uncomfortableness from adhesives, as this was outweighed by the convenience of the patch/device).

Quotes:

"I think it's a great idea. I think anything to make things simpler and easier... for the hospital, for the patient, I think it's wonderful...."

"... if someone could monitor what's happening on those weird phases with your brain, if this could see what's going on in there, that would be like a little miracle, it really would be."

"...anything that can diagnose encephalitis would be fantastic."

Anticipated concerns and queries of device implementation

1. Ability for the patch to remain in situ during acute stages of illness and patient confusion.
2. Potential side effects of the device, centred around possible irritation from device adhesives.
3. How to best approach gaining consent to use the device, especially during acute phase of illness.
4. Ensuring the correct device is used and not mistakenly employed due to a similar appearance to other devices.
5. Ensure that clinicians are well informed on the device.
6. How to fully facilitate patient involvement in their daily progress/recovery.
7. The wearability of the patch during brain scans and MRIs.
8. The acceptability of the patch when used alongside a finger prick for blood.

Summary of patient reported needs and requirements

- Ensure that the patch is placed discreetly, with sufficient adhesives, where an acutely unwell patient would be unable to reach and/or remove, without interfering with sleep.
- Consider a flexible approach to the device placement, according to the patient's stage of recovery.
- Be mindful of patient allergies or skin irritation.
- Ensure family members are debriefed on device use and applicability to gain informed consent on behalf of patients, as necessary.
- Provide comprehensive information packs to clinicians.
- Consider future design of the device storage box to distinguish the device from glucose monitors.
- Review patient follow-up procedures, e.g. implementation of patient diaries to self-monitor recovery and patient reported outcomes.
- Consider how patient progress or deterioration can be shared with family members.
- Ensure radiographers and relevant clinical staff are informed to remove the device before scans.
- Consider potential for varied acceptability e.g. due to neurodiversity/ sensory needs of patients which may impact on recovery.

Professional Working Groups

Perceived benefits of the device

1. The low cost of the device.
2. Applicability in South African, non-ICU settings: i.e.
    a. Using wearable patches for patients who are critically unwell but unable to enter high care ICU settings for monitoring in terms of the degree of or disease progression.
    b. The potential for the device to help mitigate problems with unpredictable staff ratios.
    c. Usefulness in paediatric settings where it is difficult to carry out regular blood tests.
3. Applicability in a UK setting: the device would also be useful in the paediatric population, and for patients with baseline cognitive impairment due to potential difficulty obtaining complete clinical details or collecting blood samples due to difficulty in venous access.
4. The potential for the device to predict other biomarkers e.g. to support the clinician when making decisions regarding administration of antibiotics.

Anticipated concerns and queries of device implementation

1. The potential for trust issues or hesitancy using the new, untraditional device.
2. Would specialist training be required to use the device?
3. Patient acceptability i.e. where the patch is worn and frequency of changes, patient allergies, the material of the device.
4. Within a South African setting, clinicians are currently experiencing multiple data issues and inadequate data due to storms or unreliable Wi-Fi, hence this setting lacks the infrastructure to provide continuous real time accurate data.
5. Support with interpreting results of the device.
6. Can the device be connected to the main patient data systems?
7. How will the data be stored in the South Africa setting to protect the privacy of patients?

Summary of professional reported needs and requirements

- Consider including an SD card in the device that can store data until a reliable internet connection is established for the results to be processed.
- Ensure that the device remains convenient to remove and replace and make the device accessible to as many clinical staff members as possible.
- Produce a patient information leaflet, e.g. within the consent form for the research setting, and to address common questions for use in practice, including advantages over frequent blood draws.
- Consider the type of information available from the device e.g. possibly provide information on values, trends in the plot pattern and some degree of interpretation to cater to varying clinician requirements.
- Interoperability would need to be considered in future device developments, as well as making the data available in existing clinical systems.
- Enable the device to stimulate a review for antibiotics.
- Consider using the device to predict other biomarkers e.g. Procalcitonin
- Aim to centralise the device e.g. on an app or enable various means of tracking via email or other modes, including a warning if the patient deteriorates.
- To increase data privacy in the long term, consider use of Blockchain (which is used in some health facilities within Africa).
- Consider frequency of blood samples taken during the clinical trial stages, to optimise monitoring within the practicality parameters of the study.