Realising the potential of next generation cuffless BP technology - Suggested work streams

Background information and proposal for the BIHS/IQVIA BP Tech Summit

Validation

- Define key application areas: screening, 24-hour monitoring, and treatment tracking
- Develop a live authenticated summary of devices for screening, diagnosis and treatment tracking, and associated validation status
- Summarise existing validation evidence for fitness and medical devices (CE marking, FDA 510(k), MFDS - Korean Ministry for Food and Drug Safety, CFDA - Chinese Food and Drug Administration)
- Provide interim advice for patients and health care professionals as to the limitations of existing validation evidence
- Prioritise application areas and determine whether existing validation evidence and/or proposed protocols are adequate
- Develop pragmatic validation protocols tailored to each use case as necessary
- Develop statistical frameworks: define efficacy metrics, sample size requirements (overall and subgroup), and population representativeness criteria
- Establish a framework for ongoing review and refinement

Data Integration

- Propose device data output standards
    - Minimum data output e.g. device, technology, validation status, time stamped BP and heart rate values
    - Optimal data output e.g. raw waveform data, concurrent activity, other physiological measures
    - File format standards – consideration of HL7 Fast Healthcare Interoperability Resources (FHIR) as a common standard
- Propose data presentation guidance
    - Risk presentation
    - 24-hour diagnosis standards
    - Continual monitoring and treatment monitoring standards
    - Integration with treatment data
- Pilot device to NHS App interface
- Pilot App to EHR integration for NHS App and commercial Apps

Performance and Innovation

- Explore funding models for low-cost transducers to improve accessibility
- Evaluate feasibility of linking device-specific BP data to clinical outcomes including BP control outcomes, surrogate measures of BP related cardiovascular outcomes such as target organ damage and major adverse cardiovascular events

- Pilot real-world evaluation of cuff-less devices used in parallel with cuffed devices for BP accuracy and BP control outcomes
- Examine risk prediction by cuff-less BP and other wearable data (raw waveforms, BP variability, activity and other multi-transducer data)
- Investigate creating a shared resource for developing machine learning algorithms via linkage of raw transducer data to clinical outcomes