Discussion Summary

Self-Measured Blood Pressure Monitoring: Examine a New Model to Ensure Valid Readings

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High-level Overview

The primary purposes of this discussion are to educate and inform participants on the IHMI's Self Monitored Blood Pressure 3 use case and requirements and promote the benefits of its adoption and use as well as allow participants to provide feedback.

Summary

What type of remote cuff is traditionally accepted by most clinicians?

- An oscillometric device is likely the kind most accepted by clinicians for a "remote cuff". The cuff itself is a separate issue from the measurement device. Cuffs need to be matched to the arm circumference. Usually a validated upper arm device is preferred if possible. For special populations such as people who are obese with a conical shaped arm, then a validated wrist cuff device could be an alternative.
- More clinicians, their patients, and the general public should be aware of the BP cuff device inaccuracy issue.
- BP readings should be done under the following rules to ensure accuracy.

    1. any automated device which is used on a patient MUST HAVE BEEN VALIDATED to the AAMI/ISO Standard, or the BHS protocol. No other testing can be accepted.
    2. as discussed in the ACC publication, EVERY PATIENT needs to have INDIVIDUAL VALIDATION of ANY automated readings with a "gold-standard" method, like research-grade auscultation.

- If you believe there are these weaknesses in the ISO Standard, it has been suggested that solutions can be proposed. The AAMI Committee in USA holds OPEN meetings.
- Many providers aren't aware that "recreational" devices do not accurately measure blood pressure, and others who strictly only accept upper arm BPs from validated devices, with most falling somewhere between. This reflects 1) a lack of general knowledge about the distinction between recreational, FDA cleared, and clinically validated devices, and 2) inconsistent resources and time to train patients to perform home BP monitoring correctly. If providers were aware of these distinctions between devices and time for training, most providers would only accept readings from an upper arm, validated device (except in the specific circumstances, described in others' posts, where wrist devices are necessary).

Data attributes that inform the direction of interventions and treatment plans

According to the 2017 American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines, what data elements can help clinicians make informed decisions at point of service if accompanied with the blood pressure reading?

- Data elements that matter most are the route by which data is collected, the manner and security by which data is stored, transmitted, & to whom and when that data is collated or processed for interpretation or display that most effectively influence either informed decision making, medication

adherence or lifestyle modification. According to ACC/AHA guidelines the time, frequency and position of patient are all important factors to consider.

- Ideally, as per the clinical hypertension guidelines, 24-hr ABPM is the preferred method for out-of-office BP measures. If 24-hr ABPM is not reimbursable or not tolerated/feasible, then home BP monitoring should be done for: 7 days, 2-3 measurements per day with one minute between measures, then drop the measures of the first day then average the other days' readings, as described in the Canadian Hypertension clinical guidelines: https://www.ncbi.nlm.nih.gov/pubmed/29731013. The clinician should confirm that a validated (& affordable) device is used & that the self-measurement technique is correct. It is important to mitigate reporting bias, so BP readings on a piece of paper may not necessarily be reliable. The AMA should strongly consider the BP recording mobile app., SphygmoHome by Dr. Padwal to eliminate reporting bias & also to help confirm which measures were recorded for the averaging and that extraneous/selective measures were not included. This mobile application is based on extensive clinical hypertension experience & evidence-based reasoning & it is free so it is affordable & highly reputable.
- When BP is taken at the hospital, the location is known, but we have the propensity to white coat hypertension. When BP is taken 'at home', we assume that the location is, in fact, that patient's home. But in practice, it is suspected that 'at home' BP medications may be taken in all sorts of places - while the patient is traveling on vacation, in the camper RV, at church, in the park, and elsewhere. Part of a physician's training is to identify location, as well as time of day, to the extent reasonably possible. Part of that was driven by the time of day the patient was instructed we wished they take their home BP: AM, no meds, after emptying bladder, etc. The intent was to 'capture' as realistic a 'home setting' as reasonable, allow for anticipated BP variability or out-of-range BP results to be rechecked, either within a few minutes, or later in the day.
- Device accuracy needs to be enforced and more strongly regulated by the FDA and Health Canada. Also, any health professionals who know of a licensed/cleared device that does not meet the ISO validation standard is required, by law, to report it (Form FDA 3500A MedWatch mandatory reporting form &/or the Health Canada form). Also, invalidated devices should NOT be accepted to any journal for publication claiming to be a reliable device. Invalidated devices should be pulled from the market until it meets the ISO standard and as confirmed by independent data review by hypertension device clinician experts. The fines currently in place by the federal regulatory agencies need to be more punitive for industry for companies that are deficient in adhering to mandatory regulatory reporting.
- Other aspects to consider outside of validity is device engineering, regulatory standards, art of medicine and consumer perception/opinion (both from a patient and practitioner perspective).
- The World Health Organization is working on such a theme and will ONLY consider validated devices.
- Areas where AMA is providing leadership on this issue:
    - Target BP – educate, disseminate guidelines and provide clinical tools and support to help practices optimize how patients with hypertension are diagnosed and managed. (https://targetbp.org/)
    - Digital Health Implementation Playbook – key steps, best practices and resources to accelerate the adoption and scale of digital health solutions including development and implementation of remote

patient monitoring programs. (https://www.ama-assn.org/amaone/ama-digital-health-implementation-playbook)

- Improving Health Outcomes Validated Device List. (https://wire.ama-assn.org/delivering-care/ama-aha-developing-list-validated-bp-monitors)
- IHMI – develop data models that enable identification of devices that are both 1) FDA cleared and/or 2) present on the Validated Device List, from devices that have not been validated. Provide a platform for respectful discussion of the messy reality of emerging solutions and problems in remote monitoring. (https://www.ama-assn.org/amaone/integrated-health-model-initiative-ihmi)
- Advocacy – AMA testimonies, comment letters and sign-on letters for topics including self-measured blood pressure (https://www.ama-assn.org/advocacy/physician-advocacy/federal-state-correspondence-finder)

- Many caution strongly against accepting FDA cleared devices alone. Subpar devices can easily obtain FDA clearance. There must be insistence that devices be validated and not just FDA cleared.
- The Validated Device List and the foundational work being done by the Health Outcomes team is fundamental. The hope is the VDL team's work will underpin the entire AMA IHMI blood pressure strategy.

Why should clinicians concern themselves with device provenance? How does this kind of information benefit patients, providers, and/or payers? Examples of device provenance include device identification number, brand name, and version of model.

- The benefit of tracking device provenance is to ensure the clinical validity of the devices used by patients for SMBP. The FDA 510K clearance process is inadequate, and the market is riddled with "recreational" devices that are unsupported by peer-reviewed clinical data. Without baseline criteria for device data entering the EMR, patient care will be jeopardized. Using the Universal Device ID system to block bad device data from making its way into the EMR should be a primary function of a successful clinical data model.
- The 2017 ACC/AHA/AMA National Guidelines on the management of blood pressure recommend the use of self-measured blood pressure in hypertension diagnosis and management. They also recommend the use of only validated self-measured BP data. The AMA's Health Outcomes division has published criteria that will be used to qualify devices for the AMA's Validated Device List. These are evidence based, consensus recommendations.
- There are 2 types of devices: clinical (validated) and "recreational" (not validated).
- Readers can save a lot of time if they agree that there is a simple golden rule that a device is valid only if it passes the AAMI/ISO standard.
- The ACC, the AHA, the AMA, the CDC, the APhA, Hypertension Canada, World Hypertension Congress, AAMI and ISO Standards Committee members, and from validated device manufacturers, is that non-validated BP device BP Data is not authentic, can't be trusted, and is not reproducible. Health IT leaders can't wish this away, although some appear ready for battle. Some Health IT business models are built on the premise that every piece of data (good or bad) represents a financial return. Those models will fail.

The long game in Health IT is about improved outcomes.
https://www.imedicalapps.com/2016/12/instant-blood-pressure-app-ftc/

The Integrated Health Model Initiative (IHMI) supports the use cases by specifying the data elements needed to ensure that SMBP measurements are captured at the appropriate level of granularity. What are some examples to validate that SMBP measurements are collected appropriately?

- According to Use Case 3, body position, site and laterality are levels of granularity that are considered to validate measurements.
- The use of SMBP is not new, tying in both clinician instruction at initiation with patient education and re-examination are integral components.

CPT codes for remote patient monitoring require using an FDA-cleared device. Therefore, for physicians to bill evaluated readings, the device must be cleared. The Device Identifier (DI) described in the SMBP3 Use Case will provide clearance information. Do you feel that clinicians will be more inclined to encourage their patients to use cleared devices based on this development?

- Since FDA Clearance has no bearing on clinical validity, the current CPT codes will do nothing to ensure clinical decisions are based on valid patient data. In fact, such codes will only provide more fuel to the business models of "recreational", non-validated BP devices. Once the AMA launches its announced Validated Device List, THOSE device identifiers (and only those) should qualify for reimbursement through the CPT codes. If this is not done, non-validated device data will surely populate EMR's nationwide, and most providers and patients will wrongly assume those data are valid
- The IHMI has offered to consult a group of interested parties in engaging the CPT Editorial Panel on this topic.
- The CPT code should require a validated device listed on the upcoming VDL. Then, the DI system, by identifying a validated device, will be an excellent innovation.
- The AMA's validated device listing is not yet available. It should be available in the next couple of months, tentatively November of 2019.
- When it is published, there will be widespread interest in having it be available in FHIR format, which will make it compatible with MACRA and 21st Century Cures initiatives. https://www.hl7.org/fhir/device.html
- The new interoperability protocols are certainly robust enough to track location, activity, validated device, and such in the provenance data. It is very likely to see a situation where a CPT code and reimbursement only happens if all the elements are filled out (and pass required criteria); but that is a sort of opt-in model of compliance. Having the Validated Devices List available in FHIR format will absolutely help automate filtering.

Resources

- https://www.ncbi.nlm.nih.gov/pubmed/30702492
- https://www.ncbi.nlm.nih.gov/pubmed/29731013
- https://www.ama-assn.org/amaone/ama-digital-health-implementation-playbook
- https://wire.ama-assn.org/delivering-care/ama-aha-developing-list-validated-bp-monitors
- https://www.ama-assn.org/amaone/integrated-health-model-initiative-ihmi
- https://www.ama-assn.org/advocacy/physician-advocacy/federal-state-correspondence-finder
- https://www.imedicalapps.com/2016/12/instant-blood-pressure-app-ftc/
- http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2011/Medical-Devices-and-the-Publics-Health-The-FDA-510k-Clearance-Process-at-35-Years/510k%20Clearance%20Process%202011%20Report%20Brief.pdf
- https://www.hl7.org/fhir/device.html