Promoting Medical Technology Innovation – The Role of Wireless Test Beds

Session 3: Identifying and Prioritizing Key Features, Functions and Gaps in Wireless Medical Device Test Beds

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Ideal test bed may not *a single test bed*; rather a progression from simple to complex test beds. Some of these make more sense at a manufacturer's level and the more complex testing may make more sense at a government or research center level. All the tests together do to guarantee proper operation; rather, each successive level provides a higher probability that the device will work in a complex RF environment.

HOWEVER, DON'T FORGET, THIS IS A SYSTEM. The wireless device(s), no matter how well designed and regardless of the testing, will not be safe and effective unless the network is subject to a similar rigor.

Taking a model from system integration, a system of test beds might include:

- Testing within a single PHY. The first four reasonably should be tested by the MDM for each device working with the infrastructure provider. Simulations are great for a first pass through each test as they allow for reproducible environments, but I have yet to see a simulation that can completely re-create the environment real devices.

    - Perform single-type unit testing (one device and one receiver) in a low-noise environment

    - Perform single-type unit testing (one device and one receiver) in a high-noise environment

    - Multiple single-type unit testing (many of one device / many identical receivers) in a low-noise environment

    - Multiple single-unit testing (many of one device / many identical receivers) in a high-noise environment

    - Multiple-type, single- unit integration testing (one of each type of device (many different models cellular phone or many different models of patient monitors, for example) connecting to a receiver) in a low-noise system.

    - Multiple-type, single-unit integration testing (one of each type of device (many different models cellular phone or many different models of patient monitors, for example) connecting to a receiver) in a high-noise system.

    - Multiple-type, multiple-unit integration testing (many of each type of device, many models of each device type connecting to a receiver) in a low-noise system.

    - Multiple unit integration testing testing (many of each type of device, many models of each device type connecting to multiple receivers) in a high-noise system.

- Multiple-type, multiple-unit integration testing (many of each type of device, many models of each device type connecting to multiple receivers) in a low-noise system.

- Multiple unit integration testing testing (many of each type of device, many models of each device type connecting to multiple receivers) in a high-noise system.

· Multiple system integration testing (test bed with huge amount of hospital gear from many different vendors: infusion pumps, MRI, CT, WiFi devices, BT devices, streaming video, PCs, CoWs, PACS, pt monitors, servers, industrial microwaves, different infrastructures (with different network ssettings), Wi-Fi direct, 802.11a/b/g/n/ac devices at each data rate, etc)

· Testing in the actual site.

There is an assumption there exists a definition of what it means to "pass" a test. For the first 4 unit testing options, the medical device manufacturer MDM has (or should have) the definition. However, in general, the definition of a medical device network requirements / medical grade network is vague (aka not testable, not reproducible) without inclusion of the specific testing parameters (what was the environment) and the pass fail limits. Example include: Number of each type of device, bandwidth of each device, packets per second for each device, multicast/unicast/broadcast levels, allowed jitter, latency & retries; signal level of each device in the test and SNR for each device in the test, percentage of time MDM's SLAs are NOT met, noise level of each interfering device as "heard" by both the DUT and the AP, PHY rates of each device, number of SSIDs on the AP, etc.

As IEC80001 requires of medical device manufacturers, the network requirements for the devices must be provided and *in theory*, medical device manufacturers have tested to this. The FCC might consider requiring IEC 80001-1 compliance by MDMs for each wireless medical device on an IT network and including tests to prove that the device has been tested. The IEC 80001-1 committee might considering augmenting what information the MDM provides, such as specifics about testing that was done to verify the network requirements. This might include the system loads and parameters listed in the paragraph above.