Beyond Validation: Getting Apps into Clinical Practice

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Overview

- Current U.S. status

- Regulatory backdrop

- Framework for prescribing apps
  - Education/awareness
  - Creating digital formularies
  - Workflow and EHR integration
  - Payment models
  - Patient/provider support

- Conclusions

Gordon, Landman, Zhang, and Bates, npj Digital 2020

Regulation

- In U.S., Digital Health Action Innovation plan issued by FDA

- Two main categories: SaMD—Software as a Medical Device, and SiMD—Software in a Medical Device

- Also multiple frameworks in Europe

Education/Awareness

- Training
  - Medical school
  - Post-graduate
- Especially important for prescription-only regulated apps like on-line CBT to support outpatient substance use disorder treatment
- Patients can also benefit
  - But consumer ratings don't correlate with clinical utility
  - Labeling critical

Creating digital formularies

- Traditional formularies relate to drugs

- But "digital formularies" could be highly beneficial for promoting the use of high-value apps

- Key purposes:
  - Short list of apps for a specific condition or purpose (with subcategories within condition)
  - Could be better from safety perspective
  - Could enable streamlined coverage and pricing like medication formularies
  - Could help patients know which apps are supported by organization and could interoperate with HER

- Two main risks:
  - Could result in worse pricing for patients
  - Could slow diffusion of new apps to patients

Mass General Brigham Example

- Have a relationship with Xealth
  - Makes it easy for an organization to deploy multiple apps
  - Streamlines linkage with EHR
- Still early days for us
  - BabyScripts
  - Force Therapeutics—collection of PROMs data in orthopedics
  - Many types of educational materials
  - Plan is to broaden offerings
  - But is a lot of work to vet the individual apps

Workflow and EHR integration

- In U.S., average outpatient visit is 17.4 minutes
    - Many competing priorities
- For this to work well:
    - Apps should be searchable and orderable
    - Should be integrated with clinical decision support to ensure appropriateness
    - Providers should be able to note reason for use
    - Providers should be able to enter "sig"—or label for the prescription
    - Providers should be able to prescribe parameters which can be loaded
    - App should interoperate with EHR
    - Data gathered should be viewable by patient and provider
- Many will be used long-term (e.g. for a chronic condition), but others will be short-term (e.g. for a procedure like a colonoscopy)

Payment models

- Simplest is to have patients pay
  - That is almost certainly not sufficient and could promote inequities
- Reimbursement by insurance is an attractive alternative
  - Unique reimbursement challenges—e.g. how new versions are managed and paid for
- Innovations possible
  - Could allow "trial periods"
  - Accountable care organizations could choose to pay
  - Could also be packaged with other services like drugs or devices

Patient/provider support

- Patients may need support
- Especially for high-cost, high-need patients (who could benefit most)
  - In one study we did in such patients with diabetes, only 40% could even enter their glucose
  - But all patients said they wanted to use apps
- Ochsner System (in Louisiana) uses the "O Bar," which is a physical space patients can go to get recommended digital interventions, troubleshoot issues
  - Includes mechanisms to test apps and receive digital devices like Bluetooth-enable glucose monitors

Clinical Example

- 57 YO woman presents with a hemoglobin A1c of 9.6
- Physician changes diabetic medication, but also prescribes an app which will let her track more effectively
  - Selects one which is available in Spanish and is highly rated
- Patient's data are transmitted to the practice EHR go directly to a Spanish-speaking diabetes manager who works with the primary care physician and also provides some coaching
- App is covered by her accountable care organization because it has high ratings for patients like this one
  - They realize this approach is more cost-effective than newest medications

Conclusions

- Apps are highly promising, but multiple issues must be addressed
  - Apps usually required smartphones or tablets—access is an issue, especially for older and socioeconomically disadvantaged patients
  - How apps will affect provider burnout is a concern

- New regulatory approaches as we are discussing today are critical

- Great potential for improvement but this is not yet being realized at scale