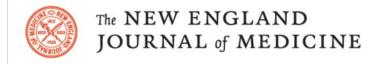


FHIR/API Connections to the Enterprise EHR Who gets to connect, and who decides?

AMDIS 2017

Russ Cucina, MD, MS
VP and Chief Health Information Officer
University of California, San Francisco



Perspective

A 21st-Century Health IT System — Creating a Real-World Information Economy

Kenneth D. Mandl, M.D., M.P.H., and Isaac S. Kohane, M.D., Ph.D. N Engl J Med 2017; 376:1905-1907 | May 18, 2017 | DOI: 10.1056/NEJMp1700235

"... approach would produce game-changing economies of scale and starkly contrast with current conditions, in which nearly all innovative applications require expensive, time-consuming, custom integrations to connect to EHRs. Physicians and patients would have access to a wide selection of software that could connect to their existing systems."



Balancing Priorities

- I think this is the future; we want to drive this open innovation
- Public mission of the University to enable creativity across California
- Academic and educational mission

But

- Privacy, security, and intellectual property considerations, and ...
- The clinical question Who decides what new apps are safe and appropriate to bring in to our clinical environment?



Who Wants to Program to our EHR APIs?

Internal

- Students & Trainees education, tinkering, and inspiration
- Faculty and Staff research and development

External

- "Founders" novice entrepreneurs with a business card and a twinkle in their eye
- (Actual) Startups
- Established Vendors seeking a development partnership





UCSF FHIR API Access Model

Read-Write in Practice

Read-Only in Practice

External Developers, Read-Only Live EHR

Internal Developers, Read-Only Live EHR

External Developers, **Sandbox** EHR



Make this barrier as low as possible



- Basic copywrite agreement, signed online Basic IP agreement, if needed, signed online







- IP agreement

- Copywrite agreement
 Network security review
 Nominal charge (\$5000?)

External Developers, **Sandbox** EHR





Comprehensive security review

Internal Developers, Read-Only Live EHR

External Developers, **Sandbox** EHR





- BAA; which is nonnegotiable and requires liability insurance
- Comprehensive security review

External Developers, Read-Only Live EHR

Internal Developers, Read-Only Live EHR

External Developers, **Sandbox** EHR



IRB (may be exempt, but we ask)

Digital Diagnostics & Therapeutics Committee

Read-Only in Practice

External Developers, Read-Only Live EHR

Internal Developers, Read-Only Live EHR

External Developers, **Sandbox** EHR



 Requires highest-level approval for EHR Governance

Read-Write in Practice

Read-Only in Practice

External Developers, Read-Only Live EHR

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External Developers, **Sandbox** EHR

What Is Clinically Safe and Appropriate?

- The Digital Diagnostics and Therapeutics Committee, the DD&T
 - the Pharmacy and Therapeutics Committee (P&T) for novel digital interventions
 - Clinical Leadership
 - Health Informatics
 - Information Systems
 - IP / Licensing
 - Integrations Team

- Risk Management
- Security
- Privacy
- Legal
- Compliance





Epic API Licensing

- Free for internal UCSF use
 - Clinical research projects
 - Professional Services / Consultants writing apps for internal only use
 - If app is given freely to another Epic organization, also free
- Commercial software must pay licensing fees to Epic
 - Licensing cost is 10-20% of company revenue derived from sales to Epic customer
 - Note: This model is new and no company has yet fully gone through the process



Example DD&T Considerations

- What is the clinical question/problem being addressed? Who will the users be?
- Does our EHR already do this?
- Does the app intend to "write" to the EHR, or "read only"?
- Are there apparent technical problems (e.g. overloading server)?
- Are there clinical workflow concerns (e.g. non-specific alerting of all providers) which should be addressed early?
- Is CHR approval required?
- What is the app's monitoring and testing plan?
- What is the plan for long-term maintenance and support of the app?
- Is integration approach aligned with regulatory and documentation integrity standards?

