Supplementary Material S1: Citation List

This citation list represents the published and gray literature reviewed during the course of the API Project.

Conflict of Interest

A.W. reports grants from the Office of the National Coordinator for Health Information Technology during the conduct of the study. D.F.S. reports grants from the Office of the National Coordinator for Health Information Technology during the conduct of the study. P.D. and N.R. report grants from the Office of the National Coordinator for Health Information Technology during the conduct of the study. K.H-H. reports grants from the Office of the National Coordinator for Health Information Technology during the conduct of the study. L.H. reports grants from the Office of the National Coordinator of Health Information Technology during the conduct of the study.

Peer-Reviewed Publications

1   Bloomfield RA Jr, Polo-Wood F, Mandel JC, Mandl KD. Opening the Duke electronic health record to apps: implementing SMART on FHIR. Int J Med Inform 2017;99:1–10. Doi: 10.1016/J.IJMEDINF.2016.12.005

2   Cohen DJ, Keller SR, Hayes GR, Dorr DA, Ash JS, Sittig DF. Integrating patient-generated health data into clinical care settings or clinical decision-making: lessons learned from Project HealthDesign. JMIR Human Factors 2016;3(02):e26. Doi: 10.2196/humanfactors.5919

3   Genes N, Violante S, Cetrangol C, Rogers L, Schadt EE, Chan YY. From smartphone to EHR: a case report on integrating patient-generated health data. NPJ Digit Med 2018;1(01):23

4   Office of the National Coordinator (ONC). Notice of Proposed Rulemaking to Improve the Interoperability of Health Information. https://www.healthit.gov/topic/laws-regulation-and-policy/notice-proposed-rulemaking-improve-interoperability-health

5   Kumar RB, Goren ND, Stark DE, Wall DP, Longhurst CA. Automated integration of continuous glucose monitor data in the electronic health record using consumer technology. J Am Med Inform Assoc 2016;23(03):532–537. Doi: 10.1093/jamia/ocv206

6   Mandl KD, Mandel JC, Kohane IS. Driving innovation in health systems through an apps-based information economy. Cell Syst 2015;1(01):8–13. Doi: 10.1016/j.cels.2015.05.001

7   Mandl KD, Mandel JC, Murphy SN, et al. The SMART platform: early experience enabling substitutable applications for electronic health records. J Am Med Inform Assoc 2012;19(04):597–603. Doi: 10.1136/amiajnl-2011-000622

8   Sanger PC, Hartzler A, Lordon RJ, et al. A patient-centered system in a provider-centered world: challenges of incorporating post-discharge wound data into practice. J Am Med Inform Assoc 2016;23(03):514–525. Doi: 10.1093/jamia/ocv183

9   Auerbach AD, Neinstein A, Khanna R. Balancing innovation and safety when integrating digital tools into health care. Ann Intern Med 2018;168(10):733–734. Doi: 10.7326/M17-3108

10 Balsari S, Fortenko A, Blaya JA, et al. Reimagining Health Data Exchange: An Application Programming Interface-Enabled Roadmap for India. J Med Internet Res 2018;20(07):e10725. Doi: 10.2196/10725

11 Burns C, Ferreira J, Hellmann TD, Maurer F. Usable results from the field of API usability: A systematic mapping and further analysis. Proc IEEE Symp Vis Lang Human-Centric Comput VL/HCC2012:179–182. Doi: 10.1109/VLHCC.2012.6344511

12 Gordon WJ, Baronas J, Lane WJ. A FHIR human leukocyte antigen (HLA) interface for platelet transfusion support. Appl Clin Inform 2017;8(02):603–611. Doi: 10.4338/ACI-2017-01-CR-0010

13 Dekel U, Herbsleb JD. Improving API documentation usability with knowledge pushing, in. 2009. Doi: 10.1109/ICSE.2009.5070532

14 Jayathilaka H, Krintz C, Wolski R Service-driven computing with APIs: Challenges and emerging trends

15 Loya SR, Kawamoto K, Chatwin C, Huser V. Service oriented architecture for clinical decision support: a systematic review and future directions. J Med Syst 2014;38(12):140. Doi: 10.1007/s10916-014-0140-z

16 Mandl KD, Kohane IS. Tectonic shifts in the health information economy. N Engl J Med 2008;358(16):1732–1737. Doi: 10.1056/NEJMsb0800220

17 Mandl KD, Kohane IS. No small change for the health information economy. N Engl J Med 2009;360(13):1278–1281. Doi: 10.1056/NEJMp0900411

18 Meng M, Steinhardt S, Schubert A. Application programming interface documentation: what do software developers want? J Tech Writ Commun 2018;48(03):295–330. Doi: 10.1177/0047281617721853

19 Public Health Service Act (PHSA) – Title 30–Health Information Technology and Quality, Section 3022 (42 USC 300jj–52)

20 Rama GM, Kak A. Some structural measures of API usability. Softw Pract Exper 2015;45(01):75–110. Doi: 10.1002/spe

21 Robillard MP. What makes APIs hard to learn? Answers from developers. IEEE Softw 2009;26(06):27–34. Doi: 10.1109/MS.2009.193

22 Scaffidi C. Why are APIs difficult to learn and use? Crossroads 2006;12(04):4. Doi: 10.1145/1144359.1144363

23 Sittig DF, Singh H. A new sociotechnical model for studying health information technology in complex adaptive healthcare systems. Qual Saf Health Care 2010;19(Suppl 3):i68–i74. Doi: 10.1136/qshc.2010.042085

24 Singh H, Sittig DF. Measuring and improving patient safety through health information technology: the Health IT Safety Framework. BMJ Qual Saf 2016;25(04):226–232. Doi: 10.1136/bmjqs-2015-004486

25 Wulf J, Blohm I. Service innovation through Application Programming Interfaces - Toward a typology of service designs. ICIS 2017 Proc 2017:1–12http://aisel.aisnet.org/icis2017/DigitalPlatforms/Presentations/8

Conflict of Interest

A.W. reports grants from the Office of the National Coordinator for Health Information Technology during the conduct of the study. D.F.S. reports grants from the Office of the National Coordinator for Health Information Technology during the conduct of the study. P.D. and N.R. report grants from the Office of the National Coordinator for Health Information Technology during the conduct of the study. K.H-H. reports grants from the Office of the National Coordinator for Health Information Technology during the conduct of the study. L.H. reports grants from the Office of the National Coordinator of Health Information Technology during the conduct of the study.

Gray Literature

1   Blue ButtonAPI. 2.0. https://bluebutton.cms.gov/

2 APIs Boost Care Coordination, Data Exchange at Northwell Health. Health IT Analytics. https://healthitanalytics.com/news/apis-boost-care-coordination-data-exchange-at-northwell-health. Published 2017

3 Bartlett J. Athenahealth buys Palo Alto software firm for $63M. Boston Business Journal. https://www.bizjournals.com/boston/news/2017/06/08/athenahealth-buys-palo-alto-software-firm-for-63m.html. Published 2017

4 Wicklund E. Can SMART on FHIR Solve mHealth's Medication Management Challenges? mHealth Intelligence. https://mhealth-intelligence.com/news/can-smart-on-fhir-solve-mhealths-medi-cation-management-challenges. Published 2017

5 Cloud G. Cloud Healthcare API. https://cloud.google.com/healthcare-api/

6 Bresnick J. Can Application Programming Interfaces Inspire a Better EHR? Health IT Analytics. https://healthitanalytics.com/features/can-application-programming-interfaces-inspire-a-better-ehr

7 Pennick J. Intermountain Healthcare Innovation Fund Invests $1M In Redox to Leverage EHR API Integration. HIT Consultant. https://hitconsultant.net/2017/04/07/intermountain-healthcare-inno-vation-fund-redox/?utm_source=TrendMD&utm_medium=cp-c&utm_campaign=HIT_Consultant__TrendMD_0. Published 2017

8 Leftwich R. Apps showcase the benefits of FHIR on the front lines of care. Intersystems. https://www.intersystems.com/wp-content/uploads/2017/04/Apps_Showcase_the_Benefits_of_FHIR_on_the_Front_Lines_of_Care_HIMSS17.pdf. Published 2017

9 The Office of the National Coordinator for Health Information Technology (ONC). Understanding emerging API-based standards. https://www.healthit.gov/isa/understanding-emerging-api-based-standards. Published 2017

10 The Office of the National Coordinator for Health Information Technology (ONC). Application Programming Interface (API) Task Force Recommendations. https://www.healthit.gov/sites/default/files/facas/HITJC_APITF_Recommendations.pdf. Published 2016

11 The Office of the National Coordinator for Health Information Technology (ONC). Key Privacy and Security Considerations for Healthcare Application Programming Interfaces (APIs). 2017;(December). https://www.healthit.gov/sites/default/files/privacy-security-api.pdf

12 AHIMA. Fundamentals of the legal health record and designated record set. http://library.ahima.org/doc?oid=104008#.XYlOJTZKjIV

13 Allscripts®. Application Store. https://allscriptsstore.cloud.prod.iapps.com/search-by-all-apps

14 Allscripts®. Developer Program. https://developer.allscripts.com/

15 Azure M. API Design. Microsoft Azure Best Practices. https://docs.microsoft.com/en-us/azure/architecture/best-practices/api-design. Published 2018

16 Apigee. Web API design: The missing link. https://pages.apigee.com/rs/351-WXY-166/images/Web-design-the-missing-link-e-book-2016-11.pdf. Published 2016

17 Apple Developer Program. Program Membership Details. https://developer.apple.com/programs/whats-included/

18 AllianceCARIN. Health Plan. https://www.carinalliance.com/our-work/health-plan/

19 AllianceCARIN. Memorandum to Payers. http://www.carinalliance.com/wp-content/uploads/2018/11/CARIN-Memorandum-to-Payers_04312018-1.pdf

20 AllianceCARIN. Trust Framework and Code of Conduct. https://www.carinalliance.com/our-work/trust-framework-and-code-of-conduct/

21 Carefluence. http://gedcportal.com/ONC-Certified-Carefluence.html

22 Centers for Medicare and Medicaid Services. CMS Blue Button 2.0. https://bluebutton.cms.gov/

23 Cerner. Code. https://code.cerner.com/

24 Cerner. App Gallery. https://code.cerner.com/apps

25 CMS. BlueButton Production API Access. CMS BlueButton 2.0. https://bluebutton.cms.gov/developers/#developer-guidelines

26 CMS. BlueButton API Docs: Developer Guidelines. https://blue-button.cms.gov/developers/#developer-guidelines

27 Deering M. Issue Brief: Patient-Generated Health Data and Health IT. 2013http://wanghaisheng.github.io/images/pghd_brief_final122013.pdf. Published 2018

28 Allscripts. Developer Program. https://developer.allscripts.com/Home/LearnMore

29 Epic. OPEN EPIC. https://open.epic.com/

30 Epic App Orchard. Explore Apps. https://apporchard.epic.com/

31 Kurtzman L. Expert Review Will Strengthen Emerging Digital Technologies. University of CaliforniaSan Franciscohttps://www.ucsf.edu/news/2018/03/410091/expert-review-will-strengthen-emerging-digital-technologies. Published 2018

32 Federal Trade Commission. Mobile Health Apps Interactive Tool. https://www.ftc.gov/tips-advice/business-center/guidance/mo-bile-health-apps-interactive-tool. Published 2016

33 Federal Trade Commission. App Developers: Start with Security. https://www.ftc.gov/tips-advice/business-center/guidance/app-developers-start-security

34 FHIR. FHIR Release 3 (STU). https://www.hl7.org/fhir/versions.html#maturity

35 HL7. FHIR® R4. http://hl7.org/fhir/history.html

36 HL7. FHIR® R4. http://hl7.org/fhir/

37 US Food and Drug Administration. Digital Health Software Pre-certification (Pre-Cert) Program. https://www.fda.gov/medical-devices/digitalhealth/digitalhealthprecertprogram/default.htm

38 Freeman R. Challenges Facing SMART on FHIR & CDS Hooks; 2018. https://www.uwfhir.org/workshops/2018/presentations/20180824-UW-FHIR-Conf-SoF-Freeman.pdf

39 Play G. Transaction Fees. https://support.google.com/googleplay/android-developer/answer/112622?hl=en

40 Health and Human Services (HHS) Office of Civil Rights. Health app developer portal. https://hipaaqsportal.hhs.gov/a/index

41 Office of the National Coordinator of Health Information Technology (ONC). Inferno. https://inferno.healthit.gov/

42 Posnack S, Barker W. Heat Wave: The US in Poised to Catch FHIR in 2019. HealthITBuzz. https://www.healthit.gov/buzz-blog/inter-operability/heat-wave-the-u-s-is-poised-to-catch-fhir-in-2019/. Published 2018

43 HL7. Argonaut Data Query Implementation Guide Version 1.0.0. http://www.fhir.org/guides/argonaut/r2/

44 HL7. Clinical Information Modeling Initiative. http://www.hl7.org/Special/Committees/cimi/overview.cfm

45 HL7. HL7 FHIR Argonaut Project. http://argonautwiki.hl7.org/index.php?title=Main_Page

46 HL7. Da Vinci Project. http://www.hl7.org/about/davinci/index.cfm

47 Slabodkin G. FHIR supporters want feds to make the standard a requirement. Health Data Management. https://www.healthda-tamanagement.com/news/fhir-supporters-want-feds-to-make-the-standard-a-requirement. Published 2017

48 HL7. Argo-Scheduling Implementation Guide CI Build. https://argonautproject.github.io/scheduling/

49 HL7. FHIR. http://www.hl7.org/FHIR/

50 HL7. FHIR Change Management and Versioning. HL7. https://www.hl7.org/fhir/versions.html#maturity

51 H.R. 34 - 21st Century Cures Act. 114th Congress (2015–2016). https://www.congress.gov/bill/114th-congress/housebill/34/text?q=%7B%22search%22%3A%5B%2221st+century+cures%22%5D%7D&r=1

52 Interopion. EHR-Integrated Solutions Simplified. https://www.interopion.com/

53 Interopion. Advancing the Latest Technologies and Development Standards. https://www.interopion.com/smartonfhir

54 Office of the National Coordinator for Health Information Technology. JASON Report Task Force to the HIT Standards and Policy Committees. https://www.healthit.gov/sites/default/files/facas/Joint_HIT_JTF%20Final%20Report%20v2_2014-10-15.pdf. Published 2014

55 Crockford D. Introducing JSON. https://www.json.org/

56 Leftwich R. Apps showcase the benefits of FHIR on the front lines of care. Intersystems. https://www.intersystems.com/wp-content/uploads/2017/04/Apps_Showcase_the_Benefits_of_FHIR_-on_the_Front_Lines_of_Care_HIMSS17.pdf. Published 2017

57 Massachusetts Department of Public Health. MASSPAT Electronic Health Record (EHR) Integration Guide: Massachusetts Prescription Monitoring Program (PMP) Version 1.2. 2017. https://cdn2.hubspot.net/hubfs/2881008/PDFDocuments/MA PMP_Welcome Packet.pdf

58 MedStar Health Research Institute. MedStar Health receives contract to pilot test patient-reported outcome data applications. 2018https://www.medstarhealth.org/mhri/news/2018/06/18/medstar-health-receives-contract-pilot-test-patient-reported-outcome-data-applications/

59 Moesif.com. API Design Patterns and Best Practices. https://www.moesif.com/blog/api-guide/api-design-guidelines/

60 MyLinks. https://www.mylinks.com/

61 OAuth 2.0. https://oauth.net/2/

62 Office of the National Coordinator for Health Information Technology. 2015 Edition Certification Companion Guide. 2015 Edition Common Clinical Data Set – 45 CFR 170.102. Available from: https://www.healthit.gov/sites/default/files/2015Ed_CCG_CCDS.pdf

63 Office of the National Coordinator for Health Information Technology. "NIH and ONC Launch the Sync for Science (S4S) Pilot: Enabling Individual health data Access and Donation." March 21, 2016. https://www.healthit.gov/buzz-blog/health-innovation/nih-and-onc-launch-the-sync-for-science-pilot/

64 Office of the National Coordinator for Health Information Technology. 2015 Edition Market Readiness for Hospitals and Health care providers. https://dashboard.healthit.gov/quickstats/pages/2015-edition-market-readiness-hospitals-health care providers.php

65 Office of the National Coordinator for Health Information Technology. Model Privacy Notice. https://www.healthit.gov/topic/privacy-security-and-hipaa/model-privacy-notice-mpn

66 Williams M, Griffiths M. GROW-Service API Clinical Safety Case and Hazard log Report. 2015:1–26

67 Pokitdok. https://pokitdok.com/

68 Polkitdok. Identify Management. https://blog.pokitdok.com/identity-management-in-healthcare-a-pokitdok-solution/

69 Posnack S, Snyder J. ONC is FHIR'd up: Unwrapping the new Inferno Testing Suite. HealthITBuzz. https://www.healthit.gov/buzz-blog/interoperability/onc-is-fhird-up-unwrapping-the-new-inferno-testing-suite/. Published 2018

70 RAIN. RAIN Live Oak Data Provenance Toolkit. https://raindataprovenance.com/. Published 2018

71 Ravindranath M. Epic chops down App Orchard fees. Politico. https://www.politico.com/newsletters/morning-ehealth/2018/10/26/epic-chops-down-app-orchard-fees-390242. Published 2018

72 Proffitt B. What APIs are and they're important. readwrite. https://readwrite.com/2013/09/19/api-defined/

73 Redox. http://developer.redoxengine.com/

74 Redox. https://www.redoxengine.com/provider-organizations/

75 Redox. https://dashboard.redoxengine.com/#/gallery/

76 Agency for Healthcare Research and Quality. A Robust Health Data Infrastructure. Prepared by JASON at the MITRE Corporation under Contract No. 13–717F-13. Rockville, MD: April 2014. AHRQ Publication No. 14–0041-EF. https://www.healthit.gov/sites/default/files/ptp13-700hhs_white.pdf

77 Sansoro. https://www.sansorohealth.com/api_intro/introduction/

78 Sansoro. Sansoro API List. https://www.sansorohealth.com/api_-list/apis/

79 SMART ® App gallery. https://apps.smarthealthit.org/

80 SMART ® . SMART App Gallery. CarePassport Portal. CarePassport Corp. https://apps.smarthealthit.org/app/paxeramed-portal

Supplementary Material S2: Key Informant Interview Protocol

KII Discussion Guide—Draft Protocol

Introductions (This page will apply to all key informant discussions)

- Introduce facilitators and participants.
- Thank participants for their time.
- ONC contracted NORC at the University of Chicago and Informatics Review LLC (the NORC team) to assist the ONC in the crucial work of ensuring the safe use of health information technology (health IT) products.
  - Under this project, NORC is *conducting an as-is assessment of the use of application programming interfaces (API) and read/write capabilities for data access and exchange.* We will use the as-is assessment to identify in which clinical scenarios the use of these read versus read/write APIs may be most appropriate, and the data elements that may be most feasible to exchange.
  - Our assessment will also include an exploration of costs associated with developing APIs, integration, and maintenance costs. We will explore both patient and provider uses of these APIs.
- A few things before we get started.
  - I [main interviewer] will be leading the discussion, but I will pause periodically to ask if our colleagues have any other questions to add.
  - We've scheduled this meeting to last 1 hour. Your participation is voluntary and you can conclude the discussion at any time. We are interested in your opinions—**It is completely okay for you not to answer any questions that you do not want to.**
  - We do have **a member of our team from NORC taking notes** so that we can write our summary. We'd also like to make an **audio recording** to help make sure we capture the entire discussion. The notes and recording will only be used by NORC to write the paper. Is that ok?
  - We won't share anything you have to say as coming from you personally. We will not include direct quotes without your permission. However, we would like to include you in the acknowledgments as someone we spoke to; would that be alright?
  - We will be conducting discussions with other experts and stakeholders. Findings from these discussions will be combined with results from our literature review and submitted to ONC as a white paper. We will summarize our findings from these discussions and nothing in our paper will be cited as coming directly from you or your company.
  - If any questions come up after we conclude today, please feel free to contact Krysta Heaney-Huls at 312–325–2510 or Heaney-Huls-Krysta@norc.org.

- The main objectives for our discussion today are to discuss:
  - Important use cases and standards for APIs. We are particularly interested in issues around safety and performance across these use cases.
  - Challenges, technical concerns, and facilitators for read and write capabilities.
  - The outlook for future development of read–write capabilities.
  - The costs associated with API development, implementation, and use.
- Do you have any questions before we begin?

Protocol Version A: Questions for API Data Providers (i.e., Implementers)

General

- Please discuss your role at [name of organization] and what work you are doing related to APIs.

Use Cases and Capabilities

First, we'd like to discuss your use cases for/experience with APIs.

- In what way are you/your organization currently working with APIs?
- What use cases are you/your organization prioritizing? Why?
- What standards are you using? Why did you select these standards?
- Does your organization currently use/support any API technology connected to your systems or systems you maintain for others using your software?
- What app features/functionalities are most important?
- What, if any, vetting procedures does your organization use to evaluate apps for potential pilots/implementation?
- What data are you concerned about in terms of threat to data if/when you allow the API connection(s)?
- Does your organization allow third-party apps to write data into your EHR system? If not, why not? If so:
  - How did you come to that decision?
  - How is that information stored or cataloged?
  - Is it accessible directly in the EHR and incorporated, including time stamps and important details? Or, is it a pdf of code or text?
- What business/contractual relationships or other interoperability arrangements does your organization have with developers of technology that connect to your API(s)? (Such tech might include, for example, direct-to-consumer or provider-facing apps, or Health IT modules such as those certified under ONC's Health IT Certification Program.)
- What policies and procedures does your organization use to monitor system performance around use of the API?

- How do you decide if a specific connection is a stress to the system?
- Does your organization use any platforms/tools to monitor use or behavior of apps connected to your API(s)? If yes, please describe.
- Does your organization support any patient-facing apps that would draw data from or write data to your system, or other organizations' systems? We are particularly interested in apps that support the automatic flow of data from medical devices; does your organization support any of these types of apps?
  - If yes, please discuss what apps and what type(s) of data can be drawn from or written to specific parts of your system.
  - For those that can write data into your system, how is the data vetted to ensure accuracy? Do you conduct any follow-up to assess safety and standards after implementation?
  - If not, what would be needed to happen to support this use cases?
- We were specifically thinking of FDA-cleared health monitoring devices for chronic conditions, like a glucose meter. Would it be desirable for frequent readings to write into the database for analysis? In what clinical contexts would this PGHD be useful to the provider?
- We would like to talk about two example scenarios related to requesting data access. What are the different considerations that would arise from?
  - Scenario A: An unaffiliated provider with a treatment relationship with a patient you've seen requests the patient's record through an API.
  - Scenario B: Your patient is using a direct-to-consumer app and requests their data through an API.
- Do you use, or have plans to use, CDS Hooks?
- What's unique or differentiates CDS Hooks from other APIs?
- In what ways are APIs likely to be most helpful in addressing interoperability? Where might they fall short?
- Priorities and challenges:
  - What priorities/requirements do you have regarding security of your systems and the privacy and security of data on them?
  - What security protocols and policies do you require as a condition of use of your API to access data from (or, if applicable, write data to) your systems?
  - What security risks exist related to API use, and what is distinct from APIs? Do they happen individually, or are they part of broader security issues?
  - What is value of OAUTH 2, given your current system?
  - What challenges have you encountered in implementation? For example, challenges with:
    - Hardware and software—Security and system performance.
    - Human–Computer interface—UI, data provenance, assessing data quality.
    - Workflow and communication—UI, workflow integration, vendor support.

- If applicable, what policies and priorities do you have regarding patient control of information?
- If applicable, what policies and priorities do you have regarding flow of patient-generated information into:
  - Clinicians' information review or other workflows.
  - Your organization's legal medical record.

- Read versus read/write development:
  - What lessons learned from pilot testing/implementation of read APIs can be extended to write APIs?
  - Do write APIs (vs. read APIs) present unique challenges related to security and/or system performance? If yes, how might these challenges be addressed?
- The future of write capabilities:
  - What data governance issues, if left unresolved, pose the greatest challenges to confidence in data quality and patient safety, and thus to widespread use of API write capabilities?
  - What technical capabilities and/or data governance resources would most likely accelerate use of write APIs in health care?
  - What other challenges exist in pursuing write capabilities?

API Openness

We'd now like to talk about the level of "openness" for the APIs you're using. For the purpose of this interview, we define "openness" in terms of ease of access to the technical documentation needed to connect to the API, any fees associated with, or other restrictions on, use of your API(s).

- How would you define/describe an "open API"?
- What would you describe as the typical or average content of technical documentation associated with published APIs that you have encountered?
- Are the APIs you are using/developing based on open standards, or are they proprietary? What are the standards used?
  - In this case, proprietary would mean that the APIs are specific to the health IT developer (e.g., EHR vendors), and not widely used.
  - Can anyone access the APIs' documentation?
- What sorts of approval or permission are needed to connect to APIs you maintain or use?
- If you did not self-develop your API, was it included with other technology you purchased or was there a separate/specific cost to obtain and implement it?
- What information, if any, are you able to share about what API cost you to build/obtain, install, and maintain?
- Is it free for other entities to connect to the APIs you offer, or is there a charge?
  - If there are charges for using an API, are the charges on an ongoing basis? Do the charges vary by any characteristics of the user or developer of the applications connecting to the API? What factors are related or specific to the interaction of an application with the API?

- E.g., volume of data transferred in total or per time period, data transfer speed supported, volume of calls to the API from the application.
  - If you are able to discuss them, are there any terms in your contract with your developer(s) that would restrict use of the API or systems to which it connects?
    - What about any terms of use between you and users of the APIs you deploy?
    - Are there terms related to protecting your or your developer's intellectual property?
    - Are components (such as libraries) related to the API released on an open source basis? If so, what under what license?

Discussion of Costs

In considering broader implementation of APIs and how the surrounding cost structure, first:

- What is driving the cost of APIs (i.e., from both the development and implementation perspective, including the cost of ongoing use)?
- Who do you foresee bearing the costs of developing APIs?
  - Of implementing/using APIs, including supporting connections for third-party apps.
- What are the costs that you incur when granting these requests? What resources do these requests demand from your system and employees?
- What would API users (e.g., app developers or app users like consumers or health care providers) be charged for?
- How would they be charged?
- Do certain cost structures make high prices and operating costs for APIs more or less likely? What strategies might help avoid a scenario in which API cost stymies information flow?

Final Thoughts

- Are there any final thoughts you'd like to share on APIs and/or interoperability?
- In what ways are APIs likely to be most helpful in addressing interoperability? Where might they fall short?

Thank you for your time.

Protocol Version B: Questions for API Technology Suppliers, API Platform Suppliers, and Third-Party Aggregators (i.e., Entitles Making APIs Available to API Data Providers and API Users)

General

- Please discuss your role at [name of organization] and what work you are doing related to APIs.

Use Cases and Capabilities

First, we'd like to discuss your use of APIs.

- In what ways is your organization currently working with APIs?
- What use cases is your organization prioritizing? Why?
- What standards are you using? Why did you select these standards?
- Does your organization currently support any API-enabled apps? If so, which ones?
  - E.g., Apple's Health Record API? What are the benefits and challenges you've encountered?
- What vetting processes does your organization follow for granting access to either open or proprietary APIs?
- What costs to the developer are associated with the registration and/or testing/validation process?
- What business/contractual relationships does your organization have related to bringing/APIs to users?
  - E.g., with developers, app providers, EHR vendors.
- What priorities/requirements do you have regarding API privacy and security?
- What policies and procedures does your organization use to ensure security of implemented apps?
- What policies and procedures do you have regarding patient control of information?
- What policies and procedures does your organization use to monitor system performance around application use? How/What works for ensuring accurate performance? Efficient performance?
- Do you conduct any follow-up to assess safety and standards after implementation?
- In what ways are APIs likely to be most helpful in addressing interoperability? Where might they fall short?
- Current challenges:
  - From your perspective, is there a predominant standard being used for APIs? If yes, please discuss.
  - Again, from your perspective, how does the timeline and process for widespread adoption of these standards available in production environments impact the use of APIs?
  - What are the most pressing challenges for API implementation and use?
  - What security risks exist related to API use, and what is distinct from APIs? Do they happen individually, or are they part of broader security issues?
  - What is value of OAUTH 2, given your current system?
  - Are there data governance or interoperability challenges for APIs that could be mitigated through the forthcoming ONC Cure Act implementation NPRM? If yes, what are they?
- Working with provider organizations, have you encountered challenges in any of the following areas that affected API implementation and/or use?
  - Human–Computer interface.
    - How does your product maintain, record, and help verify information (e.g., display data provenance to users; document and store a complete record trail, verify data accuracy)?

■ In your experience working with health care organizations that are early implementers, have you encountered any issues with system performance?
– Read versus read/write development.
  ■ What lessons learned from pilot testing/implementation read APIs can be extended to write APIs?
  ■ Do write APIs (vs. read APIs) present unique challenges related to security and/or system performance? If yes, how might these challenges be addressed?

• The future of write capabilities:
  – What data governance issues, if left unresolved, pose the greatest risk to interoperability?
  – How can challenges to confidence in data quality and potential risks to patient safety be resolved to encourage more widespread use of API write capabilities? What technical capabilities and/or data governance resources would most likely accelerate use of write APIs in health care?
  – What other challenges exist in pursuing write capabilities?

API Openness

We'd now like to talk about the level of "openness" for the APIs you're using/developing. For the purpose of this interview, we define "openness" in terms of ease of access to the technical documentation needed to connect to the API, any fees associated with, or other restrictions on, use of your API(s).

• How would you define/describe an "open API"?
• Are the APIs you are developing/using based on open standards, or are they proprietary?
  – In this case, proprietary would mean that the APIs are specific to the EHR vendor, and not widely used.
• Can anyone access the APIs? What sorts of approval or permission are needed to get access to them? What kind of documentation is made available?
• Is it free to start using the APIs, or is there a charge?
• Are there charges on an ongoing basis? Requirements for revenue sharing?
• Are there any terms that would restrict use of the system related to intellectual property?
• Are components (such as libraries) related to the API released on an open source basis? If so, under what license?
• Assuming the pieces related to the EHR vendor are sorted out, do healthcare provider organizations permit API calls, especially on behalf of patients. And do they impose any challenging restrictions on use?
• Have you considered a bulk API or bulk data transfer to support aggregate level query for these datasets? Why or why not?

Discussion of Costs

In considering broader implementation of APIs and how the surrounding cost structure, first:

• What is driving the cost of APIs, i.e., from both the development and implementation perspective?
• Who would bear the costs of APIs and health care apps?
• What is your pricing/licensing model for app developers/clients to access your APIs?
• How would they be charged?
• Do certain cost structures make high prices and barriers to information exchange more or less likely? What strategies might help avoid a scenario in which API cost stymies information flow?

Final Thoughts

• Are there any final thoughts you'd like to share on APIs and/or interoperability?

Thank you for your time.

Protocol Version C: Questions for API Users
General

• Please discuss your role at [name of organization] and what work you are doing related to APIs.

Use Cases and Capabilities

First, we'd like to discuss the health care-related use cases you're encountering for APIs and apps:

• Use cases:
  – What kind of health care uses cases are you currently developing applications for?
  – Are you prioritizing, or do you see a market preference for, certain use cases? Why?

• Prompts:
  – APIs to exchange data (e.g., clinical exchange between EHRs, registries, data warehouses).
  – APIs to contribute data to EHRs (e.g., mobile apps for PROs, PGHD).
  – APIs to aggregate data (e.g., PHRs, longitudinal records).
  – Disease-specific or setting-specific use cases.

• What standards are you using for APIs? Why did you select these standards?
• Are any of your apps currently in use by major EHR vendors, or integrating with their software, etc.?
• Please describe:
  – What, if any, vetting procedures do your apps undergo before being supported by an EHR vendor, app platform, or aggregators?
  – What business/contractual relationships do you have related to bringing apps/APIs to users, e.g., with app providers, EHR vendors?
  – What priorities/requirements do you have regarding privacy and security?
  – How do you test your app for its potential impact on system performance?
  – What policies and procedures do you have regarding patient control of information?

- Do patients have the ability to edit their data within an app? Can patient-edited information be pushed to the provider or written to the health record?
- Can patients remove information from the app or health record?
- In what ways are APIs likely to be most helpful in addressing interoperability? Where might they fall short?
- Current challenges:
  - What are the most pressing challenges for secure API implementation?
- App considerations/specifications:
  - Human–Computer interface.
- What processes do you use to address usability requirements for the Apps you develop?
- Does your app integrate with user systems like PHRs or EHRs? If yes, please explain.
- How does your app maintain, record, and help verify information, e.g., display data provenance to users; document and store a complete record trail?
- How does your app support the accurate integration of data and use of data?
- How do you mitigate concerns regarding system performance when integrating app data (potentially large volumes of data)?
- Read versus read/write development:
  - To what extent are you familiar with read APIs versus read–write?
  - Does your app provide these capabilities to users? If yes, please discuss.
  - What lessons learned from pilot testing/implementation read APIs can be extended to write APIs?
  - What gaps still need to be filled in write functionality to support audit logging, capture of data provenance, and to improve security and/or system performance?
- The future of write capabilities:
- What technical capabilities and/or data governance resources would most likely accelerate use of write APIs in healthcare?
- What other challenges exist in pursuing write capabilities?

API Openness

We'd now like to talk about the level of "openness" for the APIs you're using to develop apps. For the purpose of this interview, we define "openness" in terms of ease of access to the technical documentation needed to connect to the API, any fees associated with, or other restrictions on, use of the APIs.

- How would you define/describe an "open API"?
- What would you describe as the typical or average content of technical documentation associated with published APIs that you have encountered?
- Are the APIs you're accessing based on open standards, or are they proprietary?
  - In this case, proprietary would mean that the APIs are specific to the EHR vendor, and not widely used.
- Can anyone access the APIs' documentation? What sorts of approval or permission are needed to get access to them?
- Is it free to start using the APIs, or is there a charge?
- Are there charges on an ongoing basis? Requirements for revenue sharing?
- Are there any terms that would restrict use of the system, onerous requirements related to intellectual property?
- Are components (such as libraries) related to the API released on an open source basis? If so, under what license?

Discussion of Costs

In considering broader implementation of APIs and how the surrounding cost structure, first:

- What do you see as the major cost components for APIs?
- Who do you foresee as bearing the costs of developing, implementing, and using APIs and supporting connections to health care apps?
- What should people be charged for?
- How would they be charged?
- For example, what cost amounts or structures would inhibit your ability share data? What strategies might help avoid a scenario in which API cost stymies information flow?

Final Thoughts

Are there any final thoughts you'd like to share on APIs and/or interoperability?

Thank you for your time.