## Payment Reform in the Era of Advanced Diagnostics, Artificial Intelligence, and Machine Learning

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Abstract				

Health care is undergoing a profound transformation driven by an increase in new types of diagnostic data, increased data sharing enabled by interoperability, and improvements in our ability to interpret data through the application of artificial intelligence and machine learning. Paradoxically, we are also discovering that our current paradigms for implementing electronic health-care records and our ability to create new models for reforming the health-care system have fallen short of expectations. This article traces these shortcomings to two basic issues. The first is a reliance on highly centralized quality improvement and measurement strategies that fail to account for the high level of variation and complexity found in human disease. The second is a reliance on legacy payment systems that fail to reward the sharing of data and knowledge across the health-care system. To address these issues, and to better harness the advances in health care noted above, the health-care system must undertake a phased set of reforms. First, efforts must focus on improving both the diagnostic process and data sharing at the local level. These efforts should include the formation of diagnostic management teams and increased collaboration between pathologists and radiologists. Next, building off current efforts to develop national federated research databases, providers must be able to query national databases when information is needed to inform the care of a specific complex patient. In addition, providers, when treating a specific complex patient, should be enabled to consult nationally with other providers who have experience with similar patient issues. The goal of these efforts is to build a health-care system that is funded in part by a novel fee-for-knowledge-sharing paradigm that fosters a collaborative decentralized approach to patient care and financially incentivizes large-scale data and knowledge sharing.

Keywords: Artificial intelligence, fee-for-knowledge sharing, health-care reform, improved diagnosis, interoperability, payment models

#### INTRODUCTION

We are witnessing a golden age in health care as new diagnostic modalities coupled with artificial intelligence and machine learning (AI/ML) improve our understanding of disease and our ability to care for patients. This era is unique in that we are experiencing innovation in three synergistic areas: new data types, new data sources, and novel actionable information through data manipulation. First, an explosion in diagnostic data provides fundamentally new types of information. These data include not only the familiar "omics" and imaging data categories (although greatly extended), but they also include entirely new data types that are often generated in the patient's environment through cell phone and wearable technologies.<sup>[1,2]</sup> These new data types may be among the most informative as they offer a hitherto unavailable window into the patient's functional phenotype outside of the health-care system. Second, we are witnessing a rapid growth in data interoperability that is

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facilitating the storage and retrieval of medical information at an unprecedented scale.<sup>[3]</sup> Finally, we are witnessing growth in the field of AI/ML which holds promise in the discovery and application of new medical knowledge.<sup>[4]</sup>

#### WHERE ARE WE NOW?

While progress in these fields is encouraging, our current experience both in the implementation of electronic health-care records (EHRs) and in health-care system redesign has been disappointing. First, the current generation of EHRs

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emphasized structured data entry during provider encounters without sufficient consideration to consequences, such as the effect of real-time data entry on the physician/patient relationship.<sup>[5]</sup> Furthermore, interoperability across these systems, as well as with important diagnostic systems such as laboratory information systems and image archiving and communication systems, has been more difficult to achieve than expected.<sup>[6]</sup>

Second, it has proven difficult within the US health-care system to implement new models of care that achieve the twin goals of cost savings and improved quality of care. The experience of the Center for Medicare and Medicaid Innovation (CMMI) confirms that effective health-care system reform is challenging. Since its creation in 2011 by the Affordable Care Act, CMMI has funded numerous "models of care" in a broad range of categories.<sup>[7]</sup> However, as of this writing, only two models have been certified by the actuary of the Centers for Medicare and Medicaid Services (CMS) as saving money while providing equal or improved quality of care.<sup>[8]</sup> Similarly, in May of 2018, the General Accounting Office reported that only 4 of 37 advanced payment models reduced cost and increased quality.<sup>[9]</sup> Another study of CMMI's Bundled Payments for Care Improvement Initiative for Medical Conditions concluded that the initiative "was not associated with significant changes in Medicare payments, clinical complexity, length of stay, emergency department use, hospital readmission, or mortality."[10]

Third, our current ability to measure the quality of clinical care is inadequate. For example, 63% of physicians report that current quality measures do not capture the quality of the care they provide, even as physician practices spend an estimated \$15.4 billion annually to report measures. In a recent review, conducted by the American College of Physicians, of 86 measures, relevant for an ambulatory medicine practice and on the 2017 QPP list, 37% were valid, 35% were invalid, and 28% were of uncertain validity.<sup>[11]</sup> More distressingly, it has been known since a 2009 publication authored by individuals at CMS that "relatively few primary care physician practices are large enough to reliably measure 10% relative differences in common measures of quality and cost performance among fee-for-service Medicare patients."<sup>[12]</sup>

A central theme of this article is that these shortcomings are the result of false assumptions that underestimated the complexity of human disease while applying a centralized organizational model to quality improvement problems that require a crowdsourced knowledge-sharing environment. Humans are far more complex and diverse than manmade objects such as cars, and even when a human design flaw is scientifically understood, there is no assembly line on which to implement revised designs or dealerships to handle recalls. Similarly, the health-care delivery system itself is very complex and resistant to change. This does not mean that the current efforts are entirely useless, but rather that we need a new model where financial incentives emphasize shared problem-solving and knowledge sharing. The goal of these changes is not only to improve direct patient care but also to accelerate the adoption of advanced diagnostic technologies, interoperability, and when appropriate AI/ML.

# The Complexity of Human Disease and the Concept of Rare Patients

Humans are extremely complex organisms. Each of us consists of approximately 30 trillion cells (each with 3 billion base pairs of DNA) and an even greater number of other organisms of enormous genetic diversity.<sup>[13]</sup> As a result, we are unique, and unfortunately, current models for health-care delivery and quality measurement woefully underestimate the complexity of individual patient variation.

Studies have begun to measure the extent of this complexity. One example is a previously published study of the distribution of multiple comorbidities in the Medicare population (32 million people) using Medicare claims data from 2008.<sup>[14]</sup> This study calculated the number of disease combinations (DCs) in terms of CMS's hierarchical condition categories (HCCs). The HCC system used in this study grouped approximately 3000 ICD-9-CM codes (selected based on increase 12-month prospective expense) into 70 HCC categories. Although the HCC system is too coarsely granular to accurately describe the disease state of an individual complex patient, this level was chosen because finer levels of coding (e.g. individual ICD-9-CM codes) cause almost the entire complex population to become unique. As shown in Table 1, four groups, ranked in order of increased patient complexity, were identified. The first two groups contain the majority (68%) of patients. The third group, representing most of the cost (79%), has an average national cell size of patients with identical HCCs of approximately five individuals. The fourth group (a subset of the third) consists of about 1.66 million beneficiaries with a unique HCC combination (i.e., only one beneficiary has the given HCC combination). These beneficiaries account for 35% of expenditures. See Table 2 for examples of specific DCs.<sup>[14]</sup> Finally, a follow-up study demonstrated that the national distribution of DCs changes significantly over time with new combinations constantly emerging.[15]

Our current approach to this level of complexity is to ignore it and rely on measurement and quality improvement approaches

Table 1: Four groups of patient complexity				
Group	Percentage of Beneficiaries	Percentage of Expenditures	Estimated National Beneficiary Cell Size	
1. No HCC	35	6	Not applicable	
2. 100 most prevalent DCs	33	15	106,000	
3. Remaining 2,072,294 DCs	32	79	5	
4. 1,658,233 Unique DCs	5.1	35	1	

Table 2: Example disease combinations. Disease combinations are ranked by prevalence listing disease combinations 1 through 5 and 96 through 100. Adapted from<sup>[14]</sup>

DC Rank	Number of Beneficiaries (%)	HCC(s) describing the DC
1	1,667,891 (5.17647)	19_Diabetes without complication
2	764,522 (2.37277)	10_Breast, prostate, colorectal and other cancer
3	723,760 (2.24626)	108_COPD
4	610,943 (1.89612)	105_Peripheral vascular disease
5	531,536 (1.64968)	92_Specified heart arrhythmias
96	19,237 (0.05970)	27_Chronic hepatitis
97	19,196 (0.05958)	54_Schizophrenia and 108_COPD
98	18,806 (0.05837)	80_Congestive heart failure and 92_Specified heart arrhythmias and 131_Renal failure
99	18,754 (0.05820)	101_Cerebral palsy, other paralytic syndromes
100	18,643 (0.05786)	38_Rheum arthritis and inflammatory connective tissue disease and 55_Major depressive, bipolar, paranoid disorders

HCCs: Hierarchical condition categories, DCs: Disease combinations, COPD: Chronic obstructive pulmonary disease

that focus on prevalent disease states. This approach has serious limitations. For example, restricting analysis to the 20 most prevalent of the 70 HCCs still yields 53,476 DCs covering 40% of the population and 27% of expenditures. When added with the results of beneficiaries with no HCC [Table 1, Group 1], this prevalence-based strategy misses 25% of the population and 67% of expenditures.<sup>[14]</sup>

Twin studies offer another way of exploring individual disease variation. Specifically, monozygotic (MZ) twins are expected to have reduced variation, or increased correlation, in disease states due to their near genetic identity and shared family environment. Another published study quantified the role of heredity in the diseases found in the Medicare population using a novel methodology that compared MZ twins to dizygotic (DZ) twins while also constructing unrelated demographically matched control pairs (MCPs) for comparison to both twin sets.<sup>[16]</sup> This analysis revealed that MZ twin pairs shared 6.5% more HCCs than their MZ-MCP (26.3% vs. 19.8%) whereas DZ twins shared 3.8% more HCCs than their DZ-MCP (25.6% vs. 21.8%) with P < 0.001 for both results. While these findings may appear lower than expected, they are in line with other studies reported in the literature.<sup>[17,18]</sup> Thus, within the limits of the twin study, heredity plays a surprisingly small role in the chronic diseases found in the Medicare population. Patients, including family members, are very individual in their pattern of comorbidities.

In summary, these studies found that there is no average or typical Medicare patient. Instead, Medicare beneficiaries are characterized by a complex "long-tailed" population of DCs each of which has a small cell size even on a national level of data aggregation. Readers interested in learning more about the significance of these findings may refer to a follow-up white paper.<sup>[19]</sup>

#### THE FAILURE OF CURRENT APPROACHES

Long-tailed distributions, as opposed to normal distributions, lack useful measures of either the mean of the population or its variance. They greatly complicate the development of useful practice guidelines and clinical measures for complex patient populations, and this explains the challenges in measure development discussed above. Significantly, the studies discussed above concluded that less common diseases, in aggregate, are important drivers of comorbidities and expenditures, and explain the challenges physicians face when caring for specific patients. Even the most experienced physicians are constantly seeing new presentations and combinations of comorbidities. For example, assuming there are approximately 72,000 primary care providers,<sup>[12]</sup> then for the most prevalent DC [Table 2], there are 23 beneficiaries per provider, whereas for the 100<sup>th</sup> most prevalent DC [Table 2], there are 0.26 beneficiaries per provider.

Not even the largest health-care networks have adequate data to attempt to optimize individual care for many patients, and the "data hording" that characterizes the behavior of many medical institutions (e.g. academic medical centers) is counterproductive. As presented in Table 1, the average cell size for rare patients in the long tail of the distribution is approximately 5 nationally, and these patient clusters account for nearly 80% of expenditures. Health reform efforts must accept the fact that "rare patients" with complex combinations of disease are numerous and expensive. Current quality measures that rely on top-down centralized planning and measurement of prevalent diseases are not designed to address this issue, are often burdensome, and because they are inconsistent with the statistical properties of long-tailed distributions, cannot be significantly improved through greater funding or better implementation. Novel solutions will be required moving forward.

The US health-care system must move toward a decentralized crowdsourced environment that enables the collaborative care of the numerous small clusters of patients which confront it. Ideally, such a system would encourage providers to perform national-level searches across a high-dimensional data space that would enable a patient to be mapped to a cluster of similar patients as defined by a wide range of clinical criteria. For example, in addition to searching based on patterns of comorbidities, searches may be run to find similar patterns of cancer mutations, antibiotic resistance profiles, or patients with rare diseases. As such, a system must rely on a useful clustering of the population, and it must also prioritize the accurate diagnosis of individuals. The desire to optimize treatment will encourage patients and their providers to exchange data needed to implement this approach. Currently, the failure of the health-care system to provide a venue for data exchange encourages patients to seek information through

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social media. This undermines the value providers offer their patients and encourages behaviors that place confidential medical information at risk. While "data hording" characterizes the current health-care market, ultimately, even the largest academic health-care systems will respond to novel financial incentives discussed below.

#### **IMPROVING DIAGNOSIS**

The success of a crowdsourced information system designed to support the complex queries described above will depend on the accuracy of its diagnostic data for at least 3 reasons. First, searching for complex combinations of comorbidities will require that each individual disease was correctly diagnosed. Second, as patients age, it will be necessary to determine if new symptoms are the result of the progression of known diseases or the manifestation of a new one. Finally, we may discover correlations and even common etiologies between disease states that were previously thought to be distinct, thus changing our categorization of disease. Thus, over time, the same set of data on the same patient might be interpreted differently based on our improved scientific understanding.

Unfortunately, diagnostic errors are far too common in our health-care system to effectively support the treatment of rare patient clusters. For example, a landmark 2015 Institute of Medicine (IOM) report, entitled "Improving Diagnosis in Health Care," documented concerning rates of misdiagnosis and made numerous recommendations for improvement.<sup>[20]</sup> Moving forward, it is imperative that health reform efforts prioritize correct and timely diagnosis as a major goal and begin to implement reimbursement mechanisms that reduce diagnostic errors.<sup>[21]</sup> Similarly, it will become increasingly important to reward technologies that improve the scientific basis of diagnosis. Reimbursement will need to be provided not only for the improved molecular categorization of malignant disease, for example, but also for technologies that improve general knowledge of disease networks and disease progression. This also will require a set of health information technologies (HITs) and payment reforms which facilitate an increasingly collaborative health-care system.

#### **Artificial Intelligence and Machine Learning**

It is not this article's intention to review the field of AI/ML in health care or to characterize it as central to the reform of direct patient care (although over time it may prove to be). Of note, at least two areas of synergy should exist between a health-care system based on nationally distributed data and knowledge sharing and AI/ML. The first is the ability to find large-scale data sets to support the development and training of AI/ML-based systems. The second is the need to share information across providers so that the safety of AI/ML systems can be monitored as they are exposed to novel data sets and operating environments. Currently, AI/ML is showing promise in image-based specialties such as radiology and pathology.<sup>[22]</sup> However, AI/ML may find application in numerous other health-care problems that involve finding patterns in high-dimensional data. These may include, for example, the diagnosis of mental illness from patterns of cell phone speech,<sup>[1]</sup> the calculation of disease networks, and predictive modeling.<sup>[23,24]</sup> Thus, it is likely that AI/ML will play a role in future health care in a broad range of technologies and settings. However, these systems may require careful monitoring to protect patients from errors.

## Supporting Clinical Communication and Improved Diagnosis

To address the observations discussed above, effective health reform must support increased communications and data sharing. Specifically, providers caring for rare patients must, when appropriate, be able to search nationally for similar patients and consult with their providers. Fortunately, much work has already been done on HIT solutions that support this use case. For example, considerable work already exists in developing federated models of data to support collaborative clinical research, and these may potentially be adopted to find similar sets of patients to inform direct patient care. Examples include the Patient-Centered Outcomes Research Institute and the Observational Health Data Sciences and Informatics effort.[25,26] These efforts may be extended to support the direct patient care of the rare patient clusters discussed above (i.e., "find patients like mine"), thus offering a new level of clinical decision support based on the real-time "nearest neighbor" analysis of the "high-dimensional patient space" of large-scale populations. In addition, advances in telemedicine have the potential to enable remote consultation and care coordination. One current example of this may be Project ECHO.<sup>[27]</sup> Project ECHO is a national telehealth model for rural care that provides video clinics between specialists and community providers which focus on complex clinical populations.

In summary, our current payment models are a legacy artifact and are not optimized to apply our scientific or technical advances to further the care of the numerous patient subgroups that compose the actual population. Specifically, there is a great need for new payment models that improve information and knowledge exchange across the use cases discussed above while supporting the implementation of advanced diagnostic technologies and their associated data resources.

Moving forward, what set of payment reforms should be considered and how might they be implemented? As a straw man, this article proposes a two-stage solution. The first will be to improve the quality of diagnostic data and diagnostic workflows at the local level by implementing a new diagnostic payment model (DPM). The second stage will involve the national sharing of data and knowledge between institutions by implementing novel fee-for-knowledge-sharing (FKS) payment reforms.

#### Stage 1: Diagnostic payment models

First, given the current state of our HIT and EHR installed base,

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there is an immediate need to improve communications and the quality of clinical data at the local level with the goal of enabling interoperable access to standardized data nationally. This infrastructure should avoid the mistakes made in programs such as those associated with CMS's Meaningful Use program. For example, it is particularly important to eliminate the barriers that obstruct the free flow of information between pathology, laboratory medicine, radiology, and other sources of diagnostic information in order to optimize diagnostic workflows. A recent publication has made significant proposals to address these needs including:<sup>[21]</sup>

- 1. Changing the Medicare fee schedule to include billing codes for improved communications between pathology, radiology, and diagnostic management teams
- 2. Reducing documentation barriers and providing greater reward for cognitive work
- 3. Making accountable care organizations responsible for diagnostic timeliness and accuracy
- 4. Mandating that condition-based alternative payment models (e.g. cancer or end-stage renal disease) assume the risk of correct diagnosis.

One opportunity to advance these recommendations would be to propose changes to the fee-for-service system to the Physician-Focused Payment Model Technical Advisory Committee (PTAC).<sup>[28]</sup> The Secretary of Health and Human Services (HHS) is required to respond to models forwarded by PTAC, and models approved by the Secretary can be considered for future development.<sup>[29]</sup> Such a PTAC proposal would be a DPM. A DPM is a necessary intermediate step to enable the national implementation of standards-based communications and standardized structured data needed to support improved diagnostics at the local level as well as to provide the ability to participate in federated national databases at a later point in time. DPM payments should only be in place for a limited length of time (e.g., 10 years) and should target the implementation of both specific diagnostic technologies (e.g., advanced genomic and proteomic diagnostics as well as digital pathology) and national HIT interoperability standards.

#### Stage 2: Fee-for-knowledge sharing

While a DPM is a prerequisite, it will not enable the large-scale national knowledge sharing required to support care of the rare patient populations described above. This will require further payment reforms based on FKS that fosters new types of innovative health-care solutions. FKS must provide financial incentives for two use cases. First, when a specific patient presents with a complex problem, the patient's providers must be able to query federated databases to see if others have encountered similar findings. Organizations responding with information would be reimbursed through a micropayment for information fee schedule. Second, once the results to the query are returned, there may be a need for human-to-human knowledge sharing and group problem-solving. Payments for these activities might be based on a consultation fee for a complex office visit. In both cases, these payments are for knowledge and data sharing among different provider groups as opposed to sharing within a given provider group (which is the target of a DPM) or for a service provided to a specific patient (the goal of our current fee-for-service system). FKS payments would be structured so that a provider group only receives an FKS payment when it responds to a query from an outside group. It should be noted that FKS does not propose a centralized government repository of patient data. Under FKS, patient information will continue to be held by the patient's local provider.

This payment structure is required to support the main goal of FKS, which is to replace the current system in which providers diagnose and treat patients in an isolated environment that is uncoupled from the information available from the health-care system. The goal of FKS is to empower the members of the health-care team to find and share, in near real time, improved solutions to their specific challenges without overreliance on traditional clinical guidelines maintained by a centralized authority. This decentralization of authority, also known as "power to the edges," is a general management principle that was initially applied to military operations but has found applicability in business and other environments.<sup>[30]</sup> FKS, if properly implemented, would provide the financial incentive for the development of a new generation of clinical decision support and collaborative health-care tools.

#### Fee-for-knowledge-sharing implementation

How might FKS be implemented and what safeguards would be needed to insure it improved health care globally while not being abused? First and most importantly, the queries and patient clusters on which these payments are allowed would be defined by a neutral third party (i.e., neither payor nor provider) which would serve as a national clearinghouse by offering appropriate services including:

- 1. Serving as a center for curating the standards and data models needed to support DPM and FKS models of care
- 2. Serving as the central communication hub for submitting and executing federated queries
- 3. Adjudicating payments for FKS claims and providing a framework that allows data-sharing agreements to be enforced
- 4. Sponsoring grants, contracts, and competitions to select a set of algorithms each of which would calculate patient clusters for a variety of uses (e.g. similar molecular profiles, common patterns of comorbidities, and the presence of rare diseases).

Different provider groups would then be rewarded for sharing both data and knowledge with one another (thus eliminating self-referral as a mechanism to commit fraud). Furthermore, before a provider group would be allowed to qualify for FKS payments, it would first have to demonstrate DPM capabilities.

It might be argued that FKS will amount to a new set of expensive payments that will drive up the cost of care. While this is a risk, there are ways of mitigating it. FKS may be combined with managed care payment systems where all expenses for the direct care of specific patients would

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be capitated as is current practice. However, the various managed care organizations could earn an FKS bonus by agreeing to share data and information with one another. In this setting, FKS payments could be viewed as an adjunct to traditional risk adjustment payments. In designing such a system, some funds would be withheld for FKS payments and placed in a centralized repository. Each managed care organization would receive an allotment from this fund that is adjusted for the size and risk level of its patient population which it could spend on FKS queries to other managed care groups. It would be free to prioritize its use of these funds to maximize the cost-effectiveness and quality of its patient care. FKS payments would be structured so that the provider group only receives a payment when it responds to a query from an outside provider group (i.e., a provider cannot buy its own information). Such a hybrid system would address a key patient concern impeding the adoption of managed care more generally, namely that managed care systems are associated with narrow provider networks which limit the ability of complex patients to benefit from consultation with a broader range of knowledgeable providers. It should also be noted that managed care systems would find that the information made available to them through FKS will enable more cost-effective treatments and higher quality, thus potentially improving the use of budget and patient satisfaction. Finally, setting FKS payments at a level that would influence profitability will improve the rate and depth of knowledge sharing across the health-care enterprise and provide an economic incentive to end information blocking. CMS's Medicare Advantage Plans offer a possible environment in which to implement a national clearinghouse as described above to develop models of care that develop and test these concepts.

#### Fee-for-knowledge sharing and rare diseases

One initial way of implementing the advanced payment models discussed above is to focus on patients with rare diseases. The information requirements for caring for patients with a rare disease closely parallel the requirements for caring for the rare patient clusters discussed above. They often occur in isolation or in small patient groups making it challenging for providers to gather significant clinical experience. Furthermore, while any given rare disease may only make a small contribution to expenditures, rare diseases in aggregate place a considerable demand on the health-care system. In the United Kingdom (UK), it is estimated that 1 in 17 people has a rare disease, and rare diseases are a current focus of the UK health-care system.<sup>[31]</sup> It is important to appreciate that, while the diagnosis of a rare disease is often long, costly, and requires advanced diagnostic technologies, as a group these diseases are frequently scientifically informative.

Focusing implementation on rare diseases offers an added benefit: The approach initially avoids some scientific uncertainties in defining patient clusters. Thus, it provides time for our knowledge of disease networks and disease progression to mature. In summary, rare disease patients are a useful "North Star" in the development of the HIT infrastructure needed to implement FKS-based payment reforms.

#### Fee-for-knowledge-sharing barriers and opportunities

Many readers may view FKS as an unattainable goal pointing to prior experiences with meaningful use and other attempts at health reform. While this viewpoint is understandable, several other factors are relevant. First, as discussed above, the technical implementation of FKS is built upon two use cases that are maturing. The first is the ability to search large-scale federated databases for patients sharing specific sets of characteristics. The second is the ability of patients and providers to communicate with one another using telemedicine-based collaborative software. Thus, the technical elements that underpin FKS are increasingly within reach. Even with partial data matching between patients, it may be possible to achieve a level of useful consultations. More importantly, FKS solves the principle problem that has limited the effectiveness of previous efforts in that it provides a mechanism for providers to attempt to optimize the care of a specific patient rather than using systems that make oversimplified false assumptions regarding what the care should be, or leave the provider to figure it out without assistance. Thus, FKS is an approach that is based on the reality of the disease distribution found in the population as opposed to an idealized version of what health-care experts think we can solve.

FKS also addresses a current failure in the health-care data market in which incentives based on selling data for research or marketing purposes discourage the free flow of information between institutions. In contrast, FKS could become a disruptive force as it expands the information market to include payments for the care of rare patient groups. With appropriate data use restrictions, it should also be possible to preserve the originating institution's research rights as well.

One of the greatest opportunities presented by the payment reforms outlined in this article is to restructure traditional diagnostic workflows. The current system is characterized by silos of information not only between pathology and radiology but also across numerous other information resources (e.g., blood pressure measurements and endoscopy). Further, diagnostic workflows and communications are often ad hoc and are not well supported with our current EHR centric technologies. Fortunately, current efforts in the development of joint radiology/pathology reports, the adoption of diagnostic management teams, and the use of telemedicine in multidisciplinary settings may point the way toward a more integrated diagnostic process.<sup>[32-34]</sup> With appropriate financial incentives and continued innovations, these trends might coalesce into a broader cross-specialty field of diagnostic management systems which would be implemented by accountable care organizations as a prerequisite for FKS payment models.

FKS will also require improvements in patient privacy (both at the policy and technical levels) like those required for

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a national health-care information network. However, the current privacy policy is surprisingly flexible in permitting many of the functions that FKS requires. The Health Insurance Portability and Accountability Act (HIPAA) gives providers broad authority to exchange patient identified data when consulting with other providers regarding the care of a specific patient. HIPAA also gives payors significant flexibility to use patient data to establish new quality improvement programs when they may be important for "treatment, payment, and operations".<sup>[35]</sup> There is already considerable experience in the use of deidentified data sets to implement queries across federated databases, and the results of these queries might also be linked to the patients' providers. The providers would then be free to decide if they wished to consult with one another to further the care of the group of patients they are treating.

Perhaps, one of the greatest challenges to FKS will be the continued development and robust adoption of health-care interoperability across numerous data types. However, it is the goal of DPM reforms to incent the early adoption of these standards, an incentive the current market lacks.

Moving forward, the health-care research enterprise must support a vigorous research effort. Topics for this research may include:

- 1. Micropayment models for queries and payment models for consultations (including their potential for fraud and abuse)
- 2. The co-development of joint radiology and pathology reporting and workflows
- 3. Implementation of diagnostic management teams that align with the IOM report on diagnosis
- 4. The statistical analysis of long-tailed distributions and disease networks including patient-clustering algorithms
- 5. Clinical decision support for complex rare patients
- 6. Federated databases that support clinical research as well as direct patient care and consultation
- 7. Telemedicine technologies that support multidisciplinary consultations.

Finally, careful consideration will need to be given to ensure that mental health receives adequate attention. For example, consider DC number 97 in Table 2. This DC which consists of patients with both schizophrenia and chronic obstructive pulmonary disease (COPD) is a useful test case for collaboration between psychiatrists and pulmonary specialists. Since it is widely accepted that schizophrenics have an extremely high rate of cigarette addiction, fostering improved preventative health strategies for this vulnerable population would be a useful exercise both to reduce COPD and to develop mental health interventions more broadly.<sup>[36]</sup>

#### CONCLUSIONS

Improving the diagnostic process is an essential first step to meaningful improvements to quality, costs, and knowledge sharing as discussed above. As noted by the IOM study referenced above, the specialties of pathology and radiology are important in the current diagnostic process. Both specialties are well positioned to contribute to the future of health-care policies should they choose to do so. First, their role in the diagnostic process will only grow as new diagnostic modalities are developed and advances in AI/ML unfold. Both specialties also have considerable experience in interoperability, developing and implementing standards, and in constructing and querying complex databases. Finally, they both have considerable experience in communicating patient findings to a wide range of providers and in clinical communications generally. Thus, pathology and radiology sit astride the three revolutions discussed in this article's introduction.

Current policy approaches are limited and will need to be replaced with new ones that are aligned with the known complexity of human disease. Moving forward, it would be useful if a consortium of tertiary medical centers, state Medicaid agencies, and provider networks were to propose both DPM- and FKS-based payment models to PTAC and CMMI for further development.

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