May 29, 2020

The Honorable Diana DeGette
U.S. House of Representatives
2111 Rayburn H.O.B
Washington, DC 20515

The Honorable Fred Upton
U.S. House of Representatives
2183 Rayburn H.O.B
Washington, DC 2051

Dear Congresswoman DeGette and Congressman Upton:

On behalf of the more than 82,000 members of the American College of Surgeons (ACS), thank you for your continued leadership and interest in the 21st Century Cures Act (CURES) and for the opportunity to share additional feedback and goals as part of the “CURES 2.0” initiative. The ACS is a scientific and educational association of surgeons, founded in 1913, to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. The ACS puts the welfare of our surgical patients above all else, and we support policies and regulations that promote high-quality care, reduce the regulatory burdens placed on physicians, streamline clinical workflows, and empower patients with data.

The 21st Century Cures Act has done a great deal to advance the use of health information technology and reduce administrative burdens, among many other advances in the health care system at large. As Congress further refines “CURES 2.0,” and moves toward leveraging the knowledge and advancements made in the 21st Century Cures Act, the ACS looks forward to working together to make improvements to the health care system.

Title I: Public Health

National Testing and Response Strategy for Current and Future Pandemics

The ACS agrees that collecting data on key variables is an important part of controlling and monitoring COVID-19. ACS believes that current data registry infrastructure using standards-based data, if leveraged to store and generate knowledge across the various phases of the pandemic, could help to satisfy specific aspects of this policy goal.

A question remains: What should we take away from this national public health emergency which applies across much of surgical care? The pandemic represents a condition/disease and demonstrates how teams of clinicians come...
together to understand the basic sciences, clinical sciences and ultimately, the health care solutions for patients. For this pandemic, the focus for the teams has been both a preventive care model and a treatment model. Both prevention and treatment require extensive resources and should be a team effort if we are to successfully defeat the pandemic. In an emergency scenario, prevention and therapeutics can be informed and enhanced by sharing knowledge and lessons learned promptly. This in turn allows us to evolve the care plans and resources needed to implement those plans in real time.

It is important to note that this knowledge management structure—its processes and the data—are the same medical constructs currently used to deliver trauma care, cancer care, cardiac care and so forth. Thus, the first key takeaway is that the policy goals of CURES, as well as the incentives of payment models and other mechanism(s) used for implementation, must recognize that care is delivered to a patient by a multidisciplinary team. This team-based care is focused on the patient for their specific condition and informed by a learning health system based on the intense and reliable exchange of knowledge. These truths are the scientific method of modern care and extend beyond the silos of payment models. Therefore, the second key take-away, in order for CURES to be effective, the policy must focus on the journey from the current state to the future state of knowledge management:

1. **The current state of knowledge management must rely on the utilization of clinical data registries, including single high-fidelity source of truth (or limited sources) for a condition or disease.** In the current pandemic, using the existing digital infrastructure for surgical care, we must appreciate the value of a single source of truth (or a limited number of registry options) for a given disease or condition. For surgery, the single source is the National Surgical Quality Improvement Program (NSQIP) to aggregate data across NSQIP hospitals for a reliable and actionable source when reopening surgery in a COVID environment. NSQIP currently uses proprietary NSQIP standards which can be reliably aggregated across approximately 800 U.S. hospitals with high fidelity. NSQIP can serve as the “sole source” to reopening surgery in the current pandemic.

2. **The future state of knowledge management must move to national standards-based data.** To automate data flows across data sources (beyond registries), we must transition toward a sole
set of open source, standardized, patient-centered knowledge to all members of the team involved in the prevention model, the therapeutic care model, the resource model, and the informational data model. In surgery, knowledge management experts for surgical condition should define the sole source of standards for surgical care.

Current State: Rely on Utilizing Clinical Data Registries for a Condition or Disease

There are significant uncertainties with reopening shuttered surgical services and assuring two factors: 1. Patients receive care in a trusted surgical environment which has restored the same standards in surgical structures and processes as existed pre-pandemic; 2. The post-pandemic surgical environment has made all the necessary safety efforts related to informing patients about their care in a COVID-19 environment. COVID-19 presents its own uncertainties and risks with regards to surgical care. Reopening surgical services in a post pandemic period should involve outcomes tracking at the institutional level to serve as a single source of truth for all surgical services. Using the existing registry infrastructure will help achieve the goal of an environment of testing, shared decision making with an informed patient consent, and outcomes tracking, allowing for the nation to focus on the continuum of COVID-19 care. Collecting data will also allow the nation to share real-time knowledge in the aggregate to access the latest evidence on COVID-19 management.

ACS recommends utilizing two general registry approaches to accomplish this goal: a low burden, low cost, easy to scale registry, as well as a proven, in-depth registry; ACS has included COVID-19 variables in our high-fidelity registries, including the National Surgical Quality Improvement Program (NSQIP) registry. ACS asserts that both types of registries are needed during the pandemic to track COVID-19 cases and aggregate results.

The least burdensome approach for hospitals and surgical facilities would be a limited number of registry options with multi-specialty capability during this reopening timeframe for surgical services:

1. ACS “Core” COVID-19 Registry: Lower-burden and Low Cost for Surgical and Non-surgical COVID-19 Patients
The ACS “Core” COVID-19 Registry is currently being used to track certain aspects of care and event rates generally associated with COVID-19 patients and their overall outcomes, regardless of other co-morbidities. The low-cost, low-burden registry is being used to track certain aspects of care and event rates generally associated with COVID-19 patients and their overall outcomes but does not collect data on patient co-morbidities and or have a recognized comparative group (control).

“Core” takes a “some data are better than none” approach to learn about a disease for which little is currently known, by tracking all COVID-19 patients. Such a data registry, that every hospital is given the opportunity to report into, is free or low cost, and can scale up very quickly, is needed to capture as much relevant data as possible during the pandemic to aggregate those data. ACS utilized its extensive history of developing and maintaining clinical data registries in developing the ACS “Core” COVID-19 Registry. Cases can be batched for analysis and communicated to participating sites to inform them of their unadjusted event rates.

However, the “Core” registry has limited value since it utilizes unadjusted event rate reporting, limiting the ability to understand the risk to patients and clinicians as we re-open elective surgery. For example, this registry will lack the surgical data needed to risk adjust by condition or procedure and will not provide the information we need to safely perform procedures and inform patients of their risks when they are making the decision for surgery. For complex understanding of the uncertainties which surround COVID-19 re-opening of surgical services we need:


The ACS experience suggests that the preferred approach for re-opening surgery is to generate a COVID-19, risk-adjusted clinical data registry. A risk-adjusted registry must meet well established criteria of a meaningful and actionable registry to aggregate the data from a trusted sole source. This registry should be multi-specialty to limit the burden of data aggregation on hospitals and facilities. One example of this is the ACS NSQIP, which is already in 800 hospitals capturing inpatient cases. Leveraging the existing NSQIP registry during the pandemic will allow NSQIP hospitals to use the training, resources and infrastructure already in place with minimal added burden. This can serve as the in-patient source for understanding the risk of
surgery during the COVID-19 pandemic with real-time reporting and data remodeling on a quarterly basis. This information will be critical for shared decision-making with patients considering the risks associated with surgery during the pandemic. Without reliable and trusted data to scale immediately, such as the data collected in NSQIP, the clinical community and research community will rely on anecdotal information as they contemplate how and when to open the doors for surgery. This will be a critical source for reliable, on-demand data when elective surgery is open, and it is already up and running.

*Future State: Move to National Standards-based Data*

In the early stages of the current pandemic we learned very slowly that most of the therapeutic interventions did not work, due in-part to our nation’s reliance on a patchwork of observational data collected haphazardly in separate, proprietary data models. If these data were standards-based across the U.S., we would have had accurate data on the successes or failures of therapies weeks earlier than we did. The lack of standards caused unnecessary loss of life, suffering and wasteful use of health care resources.

Therefore, Congress should support the use of national standards-based data across the U.S. so that institutions can share and aggregate data in order to track COVID-19 and other conditions/diseases in a timely manner. Without the move towards standards-based data, registries are creating silos of data across different registries that is not based on the same standard and therefore knowledge cannot be easily aggregated or managed.

The ACS welcomes the opportunity to discuss the value of standardized data, which is further detailed under the subsection entitled “Additional Policy Considerations to Ensure a Patient Centered Approach to Digital Health.”

*COVID-19 Rare Disease Support Program*

The ACS appreciates your interest in supporting patients with rare diseases. Each year, global deaths from conditions requiring surgical care far exceed those from HIV/AIDS, tuberculosis, and malaria – combined. However, the burden of conditions requiring surgical intervention continues to be neglected as a public health strategy.
Operation Giving Back, ACS’ humanitarian arm, supports an expansion of access to surgical care for neglected surgical conditions such as cleft lip and cleft palate, club foot, cataracts, hernias, female obstetric fistulas, and untreated traumatic injuries in under-served areas both domestically and in developing countries. Expanding access to surgical care includes strengthening sustainable surgical health systems, developing trauma and disaster management systems, boosting patient care capacity, recruiting and training local surgical teams, and providing safe, timely, and affordable surgical care. Strengthening surgical health systems should also include assisting ministries of health to develop and implement national surgical, obstetric, and anesthesia plans.

Pandemic Preparedness Program for Patients

The 21st Century CURES 2.0 initiative provides the opportunity to build national systems for readiness, including a national trauma and emergency care system. While the current patchwork of local and state trauma systems provides a 24/7 response, it lacks national connectedness to enable common best practices, data standards and analysis, research, and workflow across care settings. Trauma care involves contingency planning for resource mobilization and sharing, and includes a prominent component of emergency and intensive care, and has a constant interest in better personal protective equipment. These trauma system strengths overlap with pandemic preparedness.

A national trauma system would lay the foundation for a national mass casualty response that is inclusive of mass contagious disease and that scales rapidly to save more lives while protecting the clinical workforce. Many trauma systems have developed Regional Medical Operations Centers (RMOC) that coordinate the distribution of patients across the healthcare system in the event of a disaster.¹ This framework has organized an effective response to COVID-19 across many communities by integrating a Medical Operations Coordination Cell (MOCC) with Emergency Operation Centers (EOCs) as was recently described by the Assistant Secretary for Preparedness and Response (ASPR) and the Federal Emergency Management Agency (FEMA) Healthcare Resilience Task Force.² MOCC’s coordinate the acute medical response, ensure availability of necessary care unrelated to the inciting event, and monitor for emerging outbreaks in long-term care facilities and other high risk,  

¹ https://www.facs.org/covid-19/clinical-guidance/rmoc-setup
² https://register.gotowebinar.com/recording/256769356898835472
vulnerable populations. Funding for MOCCs will strengthen community response and recovery in this ongoing pandemic while promoting community health care sector readiness for future mass casualty events.

A national trauma system would include a research infrastructure to identify and disseminate best practices in emergency and intensive care, health care worker protection, and population-based disease prevention. Further, a national trauma system with support for MOCC development would establish an interstate network of hospitals and strengthen the structural engagement between health care and public health. This system approach is an investment for enduring change that is more efficient, effective, and encompassing than patient readiness grant programs.

**Title III: Patient Engagement in Health Care Decision Making**

*Increasing Health Literacy to Promote Better Outcomes for Patients*

The ACS is supportive of encouraging the Centers for Medicare and Medicaid Services (CMS) to solicit feedback on ways to further the health literacy of an individual, particularly as it relates to approaches that can be used by Medicare or Medicaid plans or providers that reduce cost and policies that promote health insurance literacy.

The fundamental goal and purpose of health care is to create value for patients. Health literacy is an important consideration, both to slow the overall growth in health care spending and to further the goal of promoting higher value healthcare which involves both quality and cost. However, current methods of determining how much a given service is likely to cost are flawed, and do not measure the entire care episode. Further, there is little consideration of the cost of delivering care vs the cost of that care to the patient and other payers. In the context of health literacy, this is important because while a given decision may seem to reduce cost for a course of treatment, it may in fact have the opposite effect for the overall episode of care. Therefore, ACS would argue that this point should be reframed in terms of health literacy approaches that improve the value of care.

The ACS, working in partnership with the Harvard Business School’s Institute for Strategy and Competitiveness have partnered to develop ACS THRIVE, which is intended to be a superior method of defining and measuring true value in healthcare. In addition to a novel approach to measure quality, ACS
THRIVE looks at cost from both the delivery system perspective and the patient/payer perspective (utilizing the work of the PACES Center for Value in Healthcare3) to create both an internal and external view of cost. This detailed information creates a high level of transparency and can be used to help create incentives for value.

Additionally, the ACS strongly believes that value must be determined based on outcomes which accurately discriminate care delivery for things that matter to the patient. Patient-reported outcomes (PROs) are a proven way to include the patient’s voice and also support shared decision-making and informed consent. Shared decision-making is especially important when resuming surgical care in the context of a pandemic, where patients will be required to consider the risks associated with surgery. As our health system relies increasingly on PROs to support shared decision-making, it will be critical that the federal government support and promote greater health literacy among patients, as well as enhanced transparency and accountability, to ensure patient goals were elicited and met.

As digital tools continue to advance and patients are granted increasing access to health care data, it is also important that they are trusted by patients and clinicians, accessible, safe, and at the appropriate health literacy level in order to best empower patients and personalize care management. The use of digital health tools, including certified third-party applications, as discussed beginning on page 11, can be an option through which patients can access health information, communicate with their care team, and comprehend health and treatment options in easily understood terms, including videos and step-by-step guides to prepare for procedures. Digital health tools can also be used by physicians to collect information from patients to help facilitate shared decision-making and better understand the patient’s needs throughout their entire care journey.

Health literacy that helps patients understand their health status and condition, the possible courses of treatments with their respective risks and outcomes, and the terms of their insurance including the total and out-of-pocket costs likely for these treatments is vital to helping patients achieve their goals for care. Health literacy is most effective when coupled with transparent information on the value of care.

3 https://www.pacescenter.org/
Title IV: Clinical Trials

Medicaid

For cancer patients without acceptable treatment choices, enrollment in a clinical trial may offer hope for a response to a new anti-cancer therapy. Because cancer trials include the standard of care therapies, participation in a clinical trial can be an excellent treatment option. Therefore, coverage of the routine care costs associated with clinical trials, such as office visits, laboratory and other ancillary services, is critical for cancer patients.

Nearly twenty percent of Americans receive their health insurance coverage through Medicaid. However, unlike Medicare and private and commercial payers, Medicaid is not federally required to cover routine care costs for clinical trials.

The American College of Surgeons Cancer Programs and Commission on Cancer strongly support the Covering Life-saving Investigations Needed in Cancer and Other Life-threatening Conditions through Timely use of Resources for Easy and Affordable Treatment from Medicaid for Enrollees in Need Today (CLINICAL TREATMENT) Act (H.R. 913), introduced by Representatives Ben Ray Lujan (D-NM) and Gus Bilirakis (R-FL), which would align Medicaid plans with private payers and Medicare by requiring that they cover the routine care costs associated with patients enrolled in clinical trials. The associated costs are the same costs that plans would incur if a patient were treated while not participating in a clinical trial. Any experimental treatments or additional testing required because of participation in the clinical trial would be covered by the trial sponsor and would therefore have little to no impact on Medicaid budgets.

Awareness

While access to clinical trials remains a critical issue for Medicaid patients, Congress must also address a loophole that exists in the current clinical trials process for Medicare beneficiaries enrolled in Medicare Advantage (MA) and managed care plans. Currently, CMS policy requires that beneficiaries revert to

4 https://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&selectedDistributions=medicaid&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D
fee-for-service (FFS) coverage when they enroll in a clinical trial. The MA plan is required to reimburse the Medicare beneficiary for the cost difference in the out-of-pocket cost sharing between FFS and their MA plan. The consequence of this policy forces seniors enrolled in MA plans to pay for the associated costs out of pocket, which are then subject to deductibles and co-insurance and are often much higher than MA plan fees. These costs would be fully covered for individuals enrolled in traditional Medicare, thereby creating unexpected financial challenges and additional impediments for seniors on MA plans who wish to enroll in a clinical trial. Additionally, as seniors increasingly enroll in MA plans over traditional Medicare FFS plans, such a loophole disincentivizes seniors from enrolling in MA plans, which often have less expensive deductibles and coinsurance costs.

Title V: FDA

Coordinated FDA Approach on Digital

The ACS supports the Food and Drug Administration (FDA) Commissioner coordinating the work of the Center for Drug and Evaluation (CDE), the Center for Biologies and Research (CBR), and the Center for Devices and Radiological Health (CDRH) within the FDA on digital technology issues. ACS also agrees that such coordination is critical as the FDA develops multiple efforts to advance the vision of CURES on digital technologies.

While coordination within the FDA is important, we ask that Congress encourage such coordination across the Federal government as well. As various agencies, offices, and centers within the Federal government work to advance interoperability within a digital information system, standardization in data exchange “languages” across all digital health technologies is imperative. The current use of different data format standards and different versions of such standards continues to make the exchange of data challenging and expensive. For example, many digital health tools are based on the Fast Healthcare Interoperability Resources (FHIR) standard, but all technologies do not use the same version of the FHIR server (most recently FHIR server R4), thereby impeding fluid exchange of data. Instead, all Federal agencies should mandate the same data exchange standard and version for use in all programs.

Application Programming Interfaces (API) development, and certifications. CMS and the Office of the National Coordinator for Health Information Technology (ONC) have taken a major step in this direction in the recently finalized interoperability rules with the adoption of the HL7 FHIR Release 4.0.1 as the foundational standard to support data exchange via certified APIs.

As previously discussed, all digital health technologies should ultimately use a common data format standard and version to ensure uniformity for hospitals, physicians, and patients as they use EHRs, wearables, registries, and third-party applications, and other digital tools. One way to achieve this is for the federal government to provide the FHIR server and allow access for all systems to use a common implementation of the most recent FHIR server version. The widespread conformance to the same data format standard and version will remove some of the obstacles that currently stand in the way of interoperability and will allow for bi-directional data exchange across platforms. Mandated standards would ensure compatibility by providing API technology suppliers with a clear set of rules when fulfilling API requirements. This would also ensure uniformity for users of digital tools when attempting to integrate applications. Congress should support a single, nationwide, data exchange standard and version as a standardized approach will create a more cohesive data environment, and eventually lead to a more comprehensive picture of patient health data.

FDA Coordination with Foreign Regulators to Regulate and Use Digital Health Technologies

The FDA regulates Clinical Decision Support (CDS) tools that meet the definition of a medical device. Last year, the FDA issued a Draft Guidance detailing policy implementing 21st Century Cures Act criteria as they apply to the FDA’s regulation of CDS. This Draft Guidance also addressed types of CDS that meet the definition of a device (Device CDS) and would therefore normally be regulated by the FDA, but for which the FDA will choose not to regulate because the device is deemed to present a “low risk” of harm to patients. In the FDA Draft Guidance, the agency uses a risk-based categorization framework set forth by the International Medical Device Regulators Forum (IMDRF) in order to designate certain types of Device CDS as “low risk.”

ACS questions the use of this IMDRF framework. First, it was created in 2014 and is now outdated. There have been significant technological advancements
in the last 6 years and the framework does not capture the complexity and variety of new digital health tools today. The FDA also proposed to rely on the IMDRF risk categorization framework specifically for regulation of AI/ML-based software. The IMDRF framework, however, was not developed to consider the added dimensions of risk and complexity presented by AI/ML continuous learning systems. For these reasons, ACS urges Congress to encourage the FDA to coordinate with the IMDRF to update this framework in order to work toward harmonization on the regulation and use of digital health technologies.

Regarding devices that the FDA determines to be “low risk,” and therefore carved out from FDA regulation, we remain concerned that such software could in fact cause patient harm if the software:

1. Does not function in the way that it is described;
2. If the technology is flawed or not standards-based; and/or
3. If it is based on a flawed clinical algorithm.

In such cases, even software that are determined to be “low-risk” and appropriate for FDA enforcement discretion could still cause patient harm by providing or sharing inaccurate or incomplete information that is then relied on by the patient and/or clinician. As such, ACS recommends that Congress support a process within the FDA that would establish oversight of software, for which the FDA is exercising enforcement discretion, to ensure that it does not cause patient harm. This is particularly important in cases of CDS software intended for use by patients or caregivers who are less equipped to evaluate the risks of using CDS. Providing patients and their caregivers with accurate data allow them to become better informed about their options and better manage their own care.

FDA Grant-making Authority and Funding

The concept paper describes a policy that would authorize funds to enable the FDA to provide grants in the areas of innovative clinical trial design and patient focused drug development. Congress and the FDA should consider, as part of grantmaking, opportunities for clinical experts and associations to validate underlying clinical algorithms for technology that is part of a clinical trial. Software developers and technology experts are needed to confirm that the technology itself functions as described, is free of flaws, and is standards-
based. However, clinical experts are in the best position to assess whether an algorithm is clinically valid, accurate, appropriate, and up to date.

The FDA should also coordinate with other agencies to establish a certification process to assure that digital tools in development, or that are studied as part of a clinical trial are both technologically and clinically sound. Without a certification process, patients, clinicians, and other users will be left on their own to verify if a source or product is trusted. It is critical to ensure that:

1. The clinical logic used is valid, reliable, and current to make certain that the products are safe, accurate, and in alignment with clinical guidelines;
2. appropriate technical validation is used to review standards and logic; and
3. privacy certification is included to ensure that software meet privacy standards and secure protected health information (PHI).

**ACS encourages Congress to leverage the expertise of professional society organizations to certify the clinical logic used in digital tools.** As the digital era expands, it will become increasingly important that new tools being used to assist with clinical content management and knowledge curation are assessed and monitored to ensure the clinical content is reliable, valid, and current. Such tools will require governance by content experts in order to remain up to date with evidence-based practice. While it is not the FDA’s responsibility to provide this clinical governance and validation itself, it falls within the agency’s purview to establish a process to meet this need through a trusted clinical partner, and Congress should support such an effort.

ACS appreciates the FDA’s efforts toward assuring that Americans have timely access to high-quality, safe, and effective digital health products and look forward to working with Congress and the Agency to further these important goals.

**Additional Policy Considerations to Ensure a Patient Centered Approach to Digital Health**

Beyond the policy proposals presented in the concept paper, the ACS would like to offer some additional policy solutions intended to ensure a patient centered approach to digital health.
Further Enhanced Interoperability through a Vendor-agnostic, Open-source Patient Cloud.

The ACS’ long-term vision of a patient-centric care model, supported by team-based care, and rooted in a culture of continuous quality improvement, can be achieved through advanced digital technology and a standard data infrastructure. Federal support of a vendor-agnostic, open-source patient cloud architecture would shift the industry to a patient-centric system that eases the current burdens with interoperability.

The patient cloud envisioned would aggregate data through a common data model to create a single, unique, and more complete patient medical record. The cloud should incorporate FHIR standards for data exchange required in the 21st Century Cures Act, allowing health data to be exchanged bi-directionally between all systems, including EHRs, third-party applications, registries, and wearable devices through APIs. Federal support of a patient cloud will further advance interoperability, allow for the use of more advanced technologies, and empower the patient and clinician with more accurate, current, and complete data. Multiple vendors could implement a common architecture and share data across platforms, while individual commercial platforms that utilize the standard common data model can also add their own services to the cloud to meet the various needs in the markets.

Without this open-source cloud platform and common data model, the industry will remain siloed and limited by costly proprietary solutions for data exchange and aggregation.

Provide Governance to a Knowledge Repository for Standard Clinical Workflows

As a step toward achieving data consistency and standardization within the cloud, ACS recommends the creation of a knowledge repository, containing clinical care models and knowledge artifacts, housed in the National Library of Medicine (NLM), and governed at the Federal level, similar to the National Institute for Health and Care Excellence (NICE) in the United Kingdom. The care models and knowledge artifacts housed within the knowledge repository would include standard workflows for clinical

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7 https://pathways.nice.org.uk/
conditions, including the discrete data points to document throughout the process. Creating semantic standards for data collection and clinical workflows will enable the capture of consistent and accurate data across organizations and systems, increasing interoperability, and expanding digital health beyond EHR-centric models. With the curation of standardized care models, there is opportunity to incorporate advanced technology solutions such as Artificial Intelligence (AI) and Machine Learning (ML) to provide physicians with the most current clinical best practices within their source system.

ACS encourages Congress to work with specialty societies and agencies to develop a governance structure for the knowledge repository and to provide oversight to ongoing maintenance and updates to semantic standards and workflows to ensure they remain current with clinical practice guidelines. It is important to realize this construct focuses on curating surgical healthcare knowledge using standards and structured data capture in a platform separate and distinct from the EHR, such as a patient cloud. This way, the knowledge artifacts are available for supporting optimal care by sharing those artifacts back to EHRs, to registries, and other data sources.

Develop a Technology Certification Process to Ensure Patient Safety

Congress should provide guidance to agencies to develop a certification process for advanced technologies, including AI/ML, in order to ensure the safety and efficacy of new solutions. ACS recommends a certification process for technology and software that falls outside of the FDA’s purview to ensure that the product has used appropriate clinical logic, valid technology and standards, and is meeting privacy requirements. Without a certification process, patients and clinicians will be left on their own to verify if a source or product is trusted. The current openness of the third-party application market puts patient safety at risk and will create further administrative burden for clinicians.

As new elements are added to staging or to treatment, it is difficult for APIs to keep their algorithms up to date without appropriate domain experts providing the “good-cancer-keeping” seal of approval such as from the ACS Commission on Cancer. Such a Commission involves all cancer entities from across the globe and considers the cancer standards on a regular schedule. Without updates, an API could lead to a poor recommendation.
An example of a possible certification process is detailed below:

1. ONC, in partnership with societies and physician and technical expert panels, create a technology certification process for technologies that fall outside of FDA guidance and ONC Certified Electronic Health Record Technology (CEHRT) (similar to the Trusted Exchange Framework and Common Agreement [TEFCA] and the Sequoia project);
2. Specialty societies or physician panels review the products for clinical accuracy and appropriate use of the knowledge artifacts;
3. All products attest to certain minimum privacy and security requirements.

Update Patient Privacy and Confidentiality Regulations

As digital health continues to expand, privacy and security standards need to be updated to keep pace with modern technology and the innovative ways in which patients and providers access and interact with health data.

Unfortunately, the ONC and CMS interoperability and patient access final rules do not go far enough in closing these ongoing gaps. For example, they rely simply on patient education and disclosure to protect patient privacy and place much of the onus on providers and payers to educate patients on how third-party applications could use their information. Therefore, ACS urges Congress to continue working with federal agencies such as ONC, the Office for Civil Rights (OCR) and the Office of the Inspector General (OIG) to more broadly re-evaluate current enforcement mechanisms. Current regulations need to be updated to better ensure that data sharing will not occur unless a patient explicitly authorizes it and limit the extent to which third-party/direct-to-consumer applications and other non–HIPAA–covered entities can use and share patient data. Updating privacy regulations is essential for establishing patient and clinician trust of new technologies, reducing the burden of which apps appear to be a trustworthy for sharing personal health information.

Enable the Use of a Universal Patient Identifier

In order for interoperability to advance in a safe, patient-centered way, a universal patient identifier (UPI) is essential to prevent inaccurate patient matching. Inaccurate patient matching leads to adverse events, compromised
safety and privacy, inappropriate and unnecessary care and unnecessary burden on both patients and physicians. Correcting misidentification is a time consuming and expensive burden on health systems which requires them to detect and reconcile potentially dangerous duplicate patient records and improper record merges. This leads to increased health care costs, and poor oversight of fraud and abuse. Inaccurate data matching poses a significant risk to patient safety because information may be unavailable when needed or records may be merged incorrectly, leading to inappropriate treatment choices–this is especially critical as the country manages all phases of the COVID-19 pandemic.

Errors in individual data matching will be compounded with the expansion of electronic health information sharing. Further, in the absence of a UPI, algorithms are left to rely on other personal data, including, but not limited to, social security number, birthdate, address, and credit information. ACS continues to support legislative efforts to allow HHS to explore and adopt a UPI as it would help to ensure that surgeons have a safer, more accurate and consistent way of linking their patients to their health information across the continuum of care.

Thank you again for the opportunity to provide feedback as part of the Cures 2.0 initiative. ACS looks forward to working with Congress to expand on the important work of the 21st Century Cures Act. Please contact Hannah Chargin in the ACS Division of Advocacy and Health Policy at hchargin@facs.org if you have any questions or need additional information.

Sincerely,

David B. Hoyt, MD, FACS
Executive Director