Defining the Problem and Opportunity

Expanding eConsent: Advance Care Planning in the 21st Century
Defining the Problem and Opportunity

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The Naked Truth
The Price We Pay For Things Unsaid
an advocate speaks from experience
Julie Wallace
Caregiving to Careloving

A Caregiver’s journey towards understanding, acceptance...and the eventual re-discovery of love and affection

By Dave Wallace
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Consent & Advance Care Planning: The Patient Perspective
Consent & Advance Care Planning: Complex Interplay of Many Stakeholders

McMahan, Sudore; J Am Geriatr Soc. Sept. 2020
Why is ACP Important?

• Improves patient satisfaction with care and quality of life

• Less unwanted medical care aligned with wishes

• Less stress for the surrogate decision maker

ACP Realities

• ACP rates: ~ 33% for the past 10 years

• Lower among minority populations, only ~ 15-20%

• Only ~ 10-20% discussed wishes with medical provider

• Among ICU decedents, ~ 20% no ACP before death

Challenges & Opportunities

- Outdated Models
- Health Literacy
- Language Diversity
- Cultural Diversity & Disparities
- Digital Literacy
- Legal Challenges
- COVID-19 Challenges
Outdated Models of Consent and Advance Care Planning (ACP)

• **Old Consent model:** Read and sign

• **Old ACP Model:** One-time advance directive, DNR order, or checkbox

Sudore et al., Delphi Panel Consensus Definition. JPSM 2017
2020 Systematic Review Enhanced Informed Consent

• Patient consent comprehension:
  • 43% with written interventions
  • 56% with audiovisual interventions
  • 67% with multicomponent interventions
  • **100% with teach-back interventions (New Model)**

Advance Care Planning (ACP) – the Ultimate Informed Consent

• **New Model:** ACP is a *process* that supports adults at any age or stage of health in *understanding and sharing* their personal values, life goals, and preferences regarding medical care.

Sudore et al., Delphi Panel Consensus Definition. JPSM 2017
Health Literacy

YOU DON'T CALL THIS A LEGAL DOCUMENT DO YOU?

I CAN UNDERSTAND EVERY WORD OF IT!!
Health Literacy Considerations

• Average reading level in the US = 8th grade
  • Medicaid and elderly = 5th grade

• Advance directives & consent written >12th grade level

• Limited literacy = poor understanding
Consent: The Common Rule

• “It has long been recognized that under the current rules, consent forms have been growing longer and can be difficult to understand.

• They too often appear to be designed more for protecting the legal interests of institutions than for helping someone make a decision...”

Menikoff, et. al. The Common Rule, Updated. NEJM, 2017
Language Diversity

• 61 million (~20%) speak language other than English at home
  • 40 million Spanish, 3.4 million Chinese
• Non-native English speakers & diverse languages = poor understanding
Cultural Diversity & Disparities

• Non-Western views on autonomy & decision making
  • ~20% do not want to make own medical decisions

• Experiential racism & mistrust
Digital Literacy

Yet only 60% are able to send an email, fill out an online form.

73% of older adults use the Internet

Digital Literacy: Disparities

Overall: 86% Internet User & Basic Digital Literacy, 8% Internet User Only, 6% Non User

LATINO: 76% Internet User & Basic Digital Literacy, 16% Internet User Only, 8% Non User

NON-ENGLISH: 63% Internet User & Basic Digital Literacy, 26% Internet User Only, 11% Non User

65 & UP: 60% Internet User & Basic Digital Literacy, 17% Internet User Only, 23% Non User

<$25k: 53% Internet User & Basic Digital Literacy, 22% Internet User Only, 25% Non User

Source: SF Office of Digital Equity.
Digital Divide: Patient Portals

- Only 50% of patients 50-80 yrs access patient portals
  - 84% check labs
  - 37% schedule an apt
  - 26% get advice

Slide developed by Sarah Nouri, MD
The Digital Divide: Video Visits

Access
- Not own enabled devices

Digital literacy
- Not knowing how to use devices

Usability
- Hearing, speaking, seeing; cognitive impairment

38% of older adults are not ready for video visits
- Latinx: 70%
- Black: 60%
- Low SES: 67%
- Poor health: 77%

Legal Challenges

• Each state has its own AD laws

• Execution barriers
  • Not allow oral directives
  • Require witness sigs
  • and/or a notary
Addressing Challenges

PREPARE is a step-by-step program with video stories to help you:

- Have a voice in YOUR medical care
- Talk with your doctors
- Fill out an advance directive form to put your wishes in writing.

Click the video above to learn more.

Click Here to Start PREPARE
It has video stories and can help you fill out an advance directive.

Publication on eHealth Design coming soon
COVID Challenges

• Social distancing and socially isolated adults unable to get witness signatures

• Most states do not allow virtual notaries

• Many systems not set up for clinician signatures for POLST forms
Challenges & Opportunities

• Outdated Models
• Health Literacy
• Language Diversity
• Cultural Diversity & Disparities
• Digital Literacy
• Legal & Technical Challenges
• COVID-19 Challenges
Shari Ling, MD
Centers for Medicare and Medicaid Services
Deputy Chief Medical Officer
Expanding eConsent: Advance Care Planning In The 21st Century

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Deputy Chief Medical Officer
Centers for Medicare & Medicaid Services

February 24, 2021
This presentation was prepared as a tool to assist providers and is not intended to grant rights or impose obligations. Although every reasonable effort has been made to assure the accuracy of the information within these pages, the ultimate responsibility for the correct submission of claims and response to any remittance advice lies with the provider of services.

This presentation is a general summary that explains certain aspects of the Medicare Program, but is not a legal document. The official Medicare Program provisions are contained in the relevant laws, regulations, and rulings. Medicare policy changes frequently, and links to the source documents have been provided within the document for your reference.

The Centers for Medicare & Medicaid Services (CMS) employees, agents, and staff make no representation, warranty, or guarantee that this compilation of Medicare information is error-free and will bear no responsibility or liability for the results or consequences of the use of this guide.

No financial conflicts to disclose
Size and Scope of CMS Responsibilities

• CMS is the largest purchaser of health care in the world

• CMS covers 140 million people through Medicare, Medicaid, the Children’s Health Insurance Program - roughly 1 in every 3 Americans

• Medicare spending was $750B in 2018 and is expected to experience the fastest spending growth across public and private spending (7.6 percent per year over 2019-28), largely as a result of having high projected enrollment driven by demographics

• The Medicare program alone pays out over $1.5 billion in benefit payments per day

• Through various contractors, CMS processes over 1.2 billion fee-for-service claims and answers about 75 million inquiries annually
CMS Authorities & Programs

- Advanced Alternative payment models
- ACOs, PCMH, Bundles
- Multi-payer State agreements
- Prevention and Population Health
- Rapid Cycle Evaluation

- Quality Improvement Organizations
- Hospital Innovation & Improvement Networks

- Provider Enrollment
- Fraud, Waste & Abuse Prevention & Detection
- Medical Review
- Audits and Investigations

- National & Local decisions
- Mechanisms to support innovation (CED, parallel review, other)

- 1115 Waivers
- Demonstration programs
- Innovation Accelerator Program

- Medicaid and Medicare Coordination

- Value-Based Incentive Models
- Clinical Standards
- Quality & Safety Oversight
- Program Integrity
- Quality & Public Reporting
- Payment
- Coverage

- Hospitals, Home Health Agencies, Hospices, ESRD facilities

- CLIA
- Target surveys
- Quality Assurance Performance Improvement

- Hospital Inpatient Quality
- Hospital Outpatient
- In-patient psychiatric hospitals
- Cancer hospitals
- Nursing homes
- Home Health Agencies
- Long-term Care Acute Hospitals
- In-patient rehabilitation facilities
- Hospices

- Part D
- VBP hospitals, SNF, HHA, ESRD
- Payment adjustments HAC, hospital RRP
- Physician Quality Payment Program (QPP)
Advance Care planning

• Medicare Part B (Medical Insurance) covers voluntary advance care planning as part of your yearly “Wellness” visit. Medicare may also cover this service as part of your medical treatment.

• “Qualified” providers defined under Medicare Part B can report ACP codes for payment – Physicians (MD/DO), Nurse Practitioners and Physician Assistants, Clinical Nurse Specialists

• Other team members via applicable ‘incident to’ requirements ➔ All other providers (social work, psychology, chaplains) may not report codes independently
ACP Billing & Payment

Hospitals, physicians or non-physician practitioners (NPP) may bill ACP services if the practice scope and Medicare benefit category include the services described below.

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Billing Code Descriptors</th>
</tr>
</thead>
<tbody>
<tr>
<td>99497</td>
<td>Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; first 30 minutes, face-to-face with the patient, family member(s), and/or surrogate</td>
</tr>
<tr>
<td>99498</td>
<td>Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; each additional 30 minutes (List separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>

NOTE: There are no limits on the number of times you can report ACP for a given patient in a given time period.
Quality Measure

• Quality ID #47 (NQF 0326): Advance Care Plan –
  • National Quality Strategy Domain: Communication and Care Coordination
  • Meaningful Measure Area: Care is Personalized and Aligned with Patient’s Goals

• The ACP measure is in the Administrative Quality Measures Set and applies to all inpatient and outpatient Clinical Episodes included in the BPCI Advanced Model

• Inclusion of the ACP measure is especially important in the BPCI Advanced Model because many beneficiaries that trigger an episode are hospitalized for life threatening conditions and/or undergoing major medical procedures.
Goals of MM 2.0

- Utilize only quality measures of highest value and impact focused on key quality domains
- Align measures across value-based programs and across partners, including CMS, federal, and private entities
- Prioritize outcome and patient reported measures
- Transform measures to fully digital by 2025, and incorporate all-payer data
- Develop and implement measures that reflect social and economic determinants
Thank you

Shari Ling
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Resources

• 42 Code of Federal Regulations, Part 489, Subpart I (Advance Directives policy)
• 2016 Hospital Outpatient Prospective Payment Systems Final Rule (OPPS policy for ACP services) Pages 70469–70470
• 2016 Medicare Physician Fee Schedule Final Rule (Medicare PFS policy for ACP services) Pages 70955–70959
• Advance Care Planning (information for Medicare patients)
• Medicare Benefit Policy Manual Chapter 15, Covered Medical and Other Health Services, Section 280.5.1
• Medicare Claims Processing Manual Chapter 18, Preventive and Screening Services, Section 140.8
• MWV
• National Hospice and Palliative Care Organization (download your state’s advance directives)
Lenel James
*Blue Cross Blue Shield Association*
*Business Lead – Health Information Exchange and Innovation*
Expanding eConsent, Defining the Problem and Opportunity – A Payer Perspective

February 24, 2021

Lenel James, Business Lead, Health Information Exchange & Innovation
Agenda

• Industry Activities
• Regulatory Perspective
• Related Standards
Collaborative Efforts Towards FHIR Adoption

**HL7® FHIR® ACCELERATOR**
- **Payers/Providers**
- **Provider/Provider**
- **Consumers**
- **Social Determinants of Health**
- **Cancer Care and Research**

**OTHER FHIR INITIATIVES**
- **PACIO Project**
- **sequoia project**
- **IHE**

**FUNCTIONAL USE CASES**
- **CONTRACTUAL ENFORCEMENT**
  - carequality
  - commonwell

**SHARED Technical Challenges to FHIR SCALABILITY**
- Patient & Provider Identity Management
- Directory Services
- Version Identification Scale
- Exchange Process/Metadata
- Testing, Conformance & Certification
- Security

**RAPID INDUSTRY ADOPTION OF FHIR-BASED SOLUTIONS**

**CORE SERVICES**

**INFRASTRUCTURE USE CASES**

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### Da Vinci 2021 Multi-Stakeholder Membership

#### PROVIDERS
- YAMA Medical Group
- Cedars-Sinai
- HCA Healthcare
- Sutter Health
- Multicare Connected Care
- OrthoVirginia
- Providence St. Joseph Health
- OHSU
- Texas Health Resources
- UC Davis Health
- UNC Health Care

#### EHRs
- athenahealth
- Cerner
- Epic
- Healow Insights
- Veradigm

#### DEPLOYMENT
- Availity
- MIHIN
- Change Healthcare
- Cognizant

#### PAYERS
- *Anthem*
- *Blue Cross Blue Shield of Mahanaim*
- *Blue Cross Blue Shield of Tennessee*
- *Cambia*
- *Cigna*
- *GuideWell*
- *HCSC*
- *Humana*
- *Independence*
- *United Healthcare*

#### VENDORS
- casanet
- cognosante
- edifecs
- infor
- InterSystems
- juxly
- mcg
- OPTUM
- surescripts
- ZeOmega

#### INDUSTRY PARTNERS
- HIMSS
- HL7
- NCQA

*Indicates a founding member of the Da Vinci Project. Organization shown in italics Da Vinci role. Many members participate across categories.
Implementation Guides (IG) Options for Patient Directed APIs

FHIR IG
- Da Vinci Directory (PLAN NET)
- Da Vinci Formulary
- Da Vinci Payer Data Exchange PDEX* for Clinical Data
- CARIN IG for Blue Button® for Payer and Pharmacy Claims Data
- CARIN Real Time Benefit Check for Pharmacy

FHIR Resource Definition
- Patient Direct API 1/1/21
- Directory Access API
- Other related regulation

FHIR Accelerator Commentary
1. CMS has proposed use of specific guides in December, reducing burden NPRM.
2. FHIR Community is working collaboratively to ensure the specific guides meet needs of the final PAAPI rule and the proposed rule.
3. All guides are Draft Standards for Trial Use (DSTU) and approved or moving towards a published version of DSTU.
4. NOTE: Da Vinci Directory and CARIN Real Time Benefit Check for consumer facing applications does not fall under 7/1/21 Patient Directed API regulations but is catalogued in NPRM and as a resource on other proposed rules.
5. CMS has added provider to payer and payer to pharmacy requirements to leverage this subset and additional named FHIR IGs.

https://confluence.hl7.org/display/DVP/Da+Vinci+Use+Cases
Da Vinci Support of Regulation: Patient Access

Applies To

- CMS-regulated payers, specifically MA organizations
- Medicaid Fee-for-Service (FFS) programs
- Medicaid managed care plans
- CHIP FFS programs
- CHIP managed care entities and
- QHP issuers on the FFES, excluding issuers offering only Stand-alone dental plans (SADPs) and QHP issuers offering coverage in the Federally-facilitated Small Business Health Options Program (FF-SHOP)

Implement and Maintain

- A secure, standards-based (HL7 FHIR Release 4.0.1) API that allows patients to easily access their claims and encounter information, including cost, as well as a defined sub-set of their clinical information through third-party applications of their choice.
- Beginning January 1, 2021 (enforcement discretion for 6 months)
- QHP issuers on the FFES, plan years beginning on or after January 1, 2021

Security and Privacy needs

- Who is the user?
- What App/Device?
- Is transport secure?
- What may the user/role see?
- Why is the data needed?
- What has the Patient allowed?
- Where does this XY come from?
- What just happened?
Access Control Engine

- Context
  - Break-Glass
  - PurposeOfUse
  - Workflow

- FHIR API

- User
  - Role
  - Authz
  - Facility

- Patient
  - Consent
  - Care-team
  - Dellegates

- Resource
  - Sec Tags
  - Class
  - Dates

- Policies
Consent control vectors

- Timeframe of validity of the consent - can expire
- Organization consent applies to - data custodian
- Who is being authorized (or denied)
- Regulation consent applies to
- Local Policy rules this consent build upon
- PurposeOfUse - only this kind of use is allowed
- Timeframe of data publication - only data in this period
- Security Tags - sensitivity classification of the data
- Type of clinical content - using clinical vocabulary use
- Who authored the data - only data authored by
Wrap Up

• Industry Challenge & Pace of Change
• Regulatory Implication
• Maturity and Complexity Of Implications
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