Background

Consulted for Washington State Health Care Authority to help develop criteria for certifying patient decision aids.


No conflicts of interest, relevant financial relationships, or sponsorships relevant to this activity to disclose.

The views in this talk on Shared Decision Making in the United States are independent of AHRQ.
Topics

Policy
Implementation
Barriers and facilitators
There are many definitions, each with advantages and disadvantages. Here is one definition.

“Shared decision making is a process in which clinicians and patients work together to make decisions and select tests, treatments and care plans based on clinical evidence that balances risks and expected outcomes with patient preferences and values.”

(WSHCA Certifying 2017)

PDA

Patient Decision Aid (PDA)

“...high quality decision aids can engage patients in decisions that affect their health care by providing them with information they need to make an informed choice.” (WSHCA Certifying 2017)

See the latest update of the Cochrane Systematic Review on Decision aids for people facing health treatment or screening decisions. (Stacey D, Légaré F, Lewis K, et al., 2017)
SDM ≠ PDA

Shared decision making can occur without patient decision aids.

The distribution of patient decision aids is not the same as shared decision making.
Policy
Ethics


(President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1982)
Ethical foundation

“The ethical foundation of informed consent can be traced to the promotion of two values: personal well-being and self-determination.”

“Ethically valid consent is a process of shared decisionmaking based upon mutual respect and participation, not a ritual to be equated with reciting the contents of a form that details the risks of particular treatments.”

(President’s Commission 1982)
Patient is allowed to decide

“To ensure that these values are respected and enhanced, the Commission finds that patients who have the capacity to make decisions about their care must be permitted to do so voluntarily and must have all relevant information regarding their condition and alternative treatments, including possible benefits, risks, costs, other consequences, and significant uncertainties surrounding any of this information.”

(President’s Commission 1982)
Quality

Crossing the Quality Chasm: A New Health System for the 21st Century.

(Institute of Medicine, 2001)
Patient as source of control

“The patient as the source of control. Patients should be given the necessary information and the opportunity to exercise the degree of control they choose over health care decisions that affect them. The health system should be able to accommodate differences in patient preferences and encourage shared decision making.

(Institute of Medicine, 2001)
Geographic Variation in Health Care

The Dartmouth Atlas of Health Care

(Wennberg, Cooper et al, 1996)

Map 4.7. Variations in Medicare Reimbursements
Hospital referral regions that have historically received reimbursements of less than 75% of the national average (lightest green) would benefit most from a policy to equalize differences in per enrollee reimbursements in establishing the value of the Medicare voucher. Those spending 125% or more of the national average would lose the most. Equalization would eliminate subsidies that now flow from residents of low cost regions to those in high cost regions.
Which rate is right?

“Studies provide good evidence that populations in low cost regions are not sicker or in greater medical need than those in high cost regions. Costs are higher, not because better health is being achieved, but because the local health care systems have greater capacity, or because the price of medical care in these communities is higher.”

“To find out which rate is right, patients must be informed about the options and must be free to choose according to their own preferences. This section of the Atlas provides a number of examples of practice variations that can only be remedied by bringing the patient into the clinical decision making process – by reforming the doctor-patient relationship to incorporate shared decision making.”

(Wennberg, Cooper editors, et al, 1996)
National Policy

Patient Protection and Affordable Care Act (ACA)

(U.S. House of Representatives, 2010)
Affordable Care Act Funding

Sec. 3506: Program to Facilitate Shared Decision Making

- award grants or contracts to develop, update, and produce patient decision aids
- provide for the phased-in development, implementation, and evaluation of shared decision making using patient decision aids
- award grants for establishment and support of Shared Decision Making Resource Centers

(U.S. House of Representatives, 2010)
Affordable Care Act
Organizations

Some of the organizations noted in the ACA that are working on shared decision making

- Centers for Medicare and Medicaid Services (CMS)
- Agency for Healthcare Research and Quality (AHRQ)
- Patient-Centered Outcomes Research Institute (PCORI)

(U.S. House of Representatives, 2010)
CMS
Centers for Medicare and Medicaid Services

Coverage: 100 million people

- **Medicare:** 65 or older, under age 65 with certain disabilities, people of all ages with end-stage renal disease
- **Medicaid:** Low-income adults, children, pregnant women, elderly adults and people with disabilities. Administered by states, according to federal requirements. Funded jointly by states and the federal government
- **CHIP:** Children’s Health Insurance Program
- **Health Insurance Marketplace:** Allows people to shop for insurance

(Centers for Medicare & Medicaid Services (CMS), 2017)
CMS

Payment incentives for SDM

Medicare Access and CHIP Reauthorization Act (MACRA)
Quality Payment Program

◦ Advanced Alternative Payment Models (APMs)
  ◦ Consumer Assessment of Healthcare Providers and Systems CAHPS(R)
  ◦ SDM: Initially pay for reporting, then pay for performance

◦ Merit-based Incentive Payment System (MIPS)
  ◦ Choose up to six quality measures out of 271
  ◦ SDM noted explicitly for 2: Hepatitis C treatment, total knee replacement

(CMS, 2017)
CMS

Pilot Innovation Models for SDM

Pilot Preference sensitive decisions
  ◦ stable ischemic heart disease,
  ◦ hip osteoarthritis
  ◦ knee osteoarthritis
  ◦ herniated disk and spinal stenosis,
  ◦ clinically localized prostate cancer
  ◦ benign prostate hyperplasia (BPH)

Direct Decision Support (DDS) Model
  ◦ 7 organizations, approximately 700,000 Medicare beneficiaries annually

Shared Decision Making (SDM) Model
  ◦ 50 ACOs with SDM model, equal number of comparison group ACOs

(CMS, 2017)
Specific medical decisions

Payment requires (and pays for) a shared decision making visit with the use of patient decision aids before referral for screening.

- Lung cancer screening with low-dose CT.
- Left appendage occlusion, only a nonoperating clinician can counsel patients through shared decision making.

(CMS, 2017)
AHRQ
Agency for Healthcare Research and Quality

Produces evidence to make health care safer, higher quality, more accessible, equitable, and affordable.

Works within the U.S. Department of Health and Human Services and with other partners to make sure that the evidence is understood and used.

(AHRQ, 2017)
AHRQ
SHARE Approach, Training

Developed SHARE Approach

Nationwide program for training on shared decision making

Delivered training nationwide to 948 people

Described in detail in separate presentation about AHRQ and SHARE
PCORI funds research that can help patients and those who care for them make better-informed decisions about the healthcare choices they face every day, guided by those who will use that information.

Grants:

- Implementing Shared Decision Making: $6,500,000 US
- Developing Measures of Shared Decision Making: $8,400,000 US

(PCORI 2017)
State Legislation

In addition to United States federal policy, some individual states have laws about shared decision making.

Washington State is one example.
Washington State
Washington state law: RCW 7.70.060

Defines “shared decision making” and “patient decision aid”

Affords a higher level of protection in informed consent liability actions when shared decision making is used following state requirements

Recognizes both state and nationally certified patient decision aids

Enables the medical director of the Washington State Health Care Authority to certify decision aids

(WSHCA Certifying 2017)
Washington State
Patient Decision Aid Certification

Patient Decision Aid (PDA) Certification Criteria

◦ 15 criteria for all PDAs, plus 6 additional for screening tests
◦ Based on quality standards published by the International Patient Decision Aids Standards Collaboration (IPDAS)
◦ Developed in collaboration with local and national experts and stakeholders

See handouts
◦ WSHCA Shared Decision Making
◦ Certification criteria for patient decision aids

(WSHCA Shared 2017)
Washington State
Certified patient decision aids

Currently focused on one area each year
  ◦ Year 1: Maternity focus, 5 decision aids certified
  ◦ Year 2: Joint replacement and spinal care
  ◦ Year 3: End-of-life care

First PDA certification process in the United States.

Criteria and process helped inform that National Quality Forum in their approaches to certification. (National Quality Forum (NQF), 2016)
Implementation
Implementation

The US does not have one central organization that coordinates work on shared decision making and patient decision aids.

Many groups across the country have led advances in SDM.

These groups collaborate with international SDM and PDA organizations.

The National Quality Forum is working on patient decision aid standards and measures. (NQF 2016)
International: IPDAS

US learns from and collaborates with international organizations

International Patient Decision Aid Standards (IPDAS)

Purpose:

“To enhance the quality and effectiveness of patient decision aids by establishing a shared evidence-informed framework with a set of criteria for improving their content, development, implementation, and evaluation.” (IPDAS 2017)
International: OHRI

Ottawa Hospital Research Institute (OHRI) Patient Decision Aids

Mission

◦ To explore better ways to help patients make "tough" healthcare decisions.
◦ To explore better ways to help practitioners support patients making "tough" healthcare decisions.
◦ Research: Systematic investigations

(Ottawa Hospital Research Institute (OHRI), 2017)
National Quality Forum

Not-for-profit, nonpartisan group
Receives government, nonprofit and private funding.
Formed in 1999 to support patient protections and healthcare quality through measurement and public reporting.

National Standards for the Certification of Patient Decision Aids

- 2016 Report
- Approaches to measuring the quality of decision making
- Guidance to support the development of measures to assess the impact of shared decision making.

(NQF 2016, 2017)
Many types of organizations are involved explicitly with shared decision making. These include:

- Research institutes
- Patient decision aid developers (companies, nonprofit organizations)
- Health care providers (individuals, hospitals, care networks)
- Purchasers of health care (payors, insurers)
- Combined provider and payer (accountable care organizations)
- Government agencies
- Authors of guidelines and clinical policy
“puzzle”, 2008, by Olga Berrios, 2008, licensed under CC BY 2.0
Examples of organizations

This list is not complete or prioritized, and is not an endorsement of any specific group.

Research and health care organizations include:
- Mayo, Group Health (now Kaiser), Dartmouth, Yale, University of Colorado

Government agencies include:
- CMS, AHRQ, PCORI, individual state programs

Other developers of SDM services and PDAs include:
- Healthwise, Option Grid Collaborative -> EBSCHO, HealthDialog

Many people active in SDM collaborate across multiple organizations.
Decision aids prototypes

- Diabetes, Statins, Osteoporosis, Depression, Acute myocardial infarction in the emergency department (Mayo Clinic 2017)


- Randomized trial, usual care ($n = 37$), receiving decision aid ($n = 48$)
- Patients found the tool more helpful, had improved knowledge and had more involvement in making decisions
- At 6-month follow-up, both groups had nearly perfect medication use with better adherence and no significant impact on HbA(1c) levels.
### Weight Change
- **Metformin**: None
- **Insulin**: 4 to 6 lb. gain
- **Glitazones**: Not recommended
- **Exenatide**: 3 to 6 lb. loss
- **Sulfonylureas**: 2 to 4 lb. gain

### Low Blood Sugar (Hypoglycemia)
- **Metformin**: None
- **Insulin**: Cosecutive %
- **Glitazones**: 1%
- **Exenatide**: 1 to 2%
- **Sulfonylureas**: 2 to 4%  

### Blood Sugar (A1C Reduction)
- **Metformin**: 1 to 2%
- **Insulin**: Cosecutive%
- **Glitazones**: 1%
- **Exenatide**: 1 to 2%
- **Sulfonylureas**: 2 to 4%

### Daily Routine
- **Metformin**: 0.5 to 1.5 mg, 2 to 3 times daily
- **Insulin**: 1 dose daily
- **Glitazones**: 1 mg daily
- **Exenatide**: 1 mg daily
- **Sulfonylureas**: 1 mg daily

### Daily Sugar Testing (Monitoring)
- **Metformin**: 0.5 to 1.5 mg, 2 to 3 times daily
- **Insulin**: 1 dose daily
- **Glitazones**: 1 mg daily
- **Exenatide**: 1 mg daily
- **Sulfonylureas**: 1 mg daily

### Side Effects
- **Metformin**: No other side effects associated with insulin.
- **Insulin**: Not associated with diabetes.
- **Glitazones**: Not associated with diabetes.
- **Exenatide**: Not associated with diabetes.
- **Sulfonylureas**: Not associated with diabetes.

---

(Mayo Clinic, 2017)
Effectiveness of the Chest Pain Choice decision aid in emergency department patients with low-risk chest pain: study protocol for a multicenter randomized trial. (Anderson RT, Montori VM, Shah ND et al., 2014)
Group Health

Group Health Demonstration Project 2009 – 2011

- Consumer-governed health system that integrates care and coverage for more than 660,000 patients
- Distributed 27,000 decision aids for 12 preference-sensitive surgical conditions
- Video and written material, provided for free by the Informed Medical Decisions Foundation and Health Dialog.

Results

- Successful integration into clinical practice
- Results suggested improved patient satisfaction and cost effectiveness, but study had significant limitations.

(King J, Moulton B. 2013)

Note: Group Health is now part of Kaiser Permanente
New article in 2013

- Series of interviews conducted with key stakeholders

Five key lessons for successful implementation:

- Patients need to be invited to participate in treatment decisions
- Shared decision making can affect unwarranted practice variation
- Effective integration requires leadership at all levels
- Constant evaluation and iterative improvement is necessary
- Shared decision making should be embedded in physician training and culture

(King J, Moulton B. 2013)
Option Grid(TM) PDAs

Option Grid(TM) patient decision aids (Dartmouth 2017)
- Option Grid Collaborative (international)
- Paper and online versions
- Past report of 47 PDAs on OHRI inventory (ORHI 2017)
- Some still available for free under a Creative Commons license
- EBSCO Health will now develop and distribute Option Grid™ PDAs.

Maternity aid certificated by WSHCA (WSHCA Shared 2017)
- Amniocentesis test: yes or no?
# Amniocentesis test: yes or no?

Use this decision aid to help you, your partner, and your healthcare professional decide whether or not to have amniocentesis testing. An amniocentesis test tells you whether your baby has a chromosome-related problem, such as Down syndrome. The amniocentesis test is optional. This decision aid is for women in their fifteenth week of pregnancy or later.

### Frequently Asked Questions

<table>
<thead>
<tr>
<th>Having amniocentesis</th>
<th>Not having amniocentesis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What happens during an amniocentesis test?</strong></td>
<td>The test takes place around week 15 of pregnancy. A doctor uses a needle to remove a small amount of amniotic fluid that surrounds the baby. The fluid is then tested for chromosome problems. Some women have cramps during and after the test, but can go back to normal activities the next day.</td>
</tr>
<tr>
<td><strong>Will we find out for sure if our baby has Down syndrome or another chromosome problem?</strong></td>
<td>Yes. Amniocentesis is very accurate. A positive test result means that it is very likely that your baby has Down syndrome or another chromosome problem, such as Edward’s or Patau’s syndromes. If you have a normal result, your baby most likely does not have a chromosome problem. However, not all chromosome problems can be detected by the amniocentesis test.</td>
</tr>
<tr>
<td><strong>Are there any risks to the baby?</strong></td>
<td>Amniocentesis causes less than 1 in every 100 women (less than 1%) to miscarry. This risk is in addition to the usual small risk of miscarriage for women at this point in pregnancy. A serious infection happens in about 1 in 1000 women (0.1%) who have amniocentesis.</td>
</tr>
<tr>
<td><strong>If a problem is found, what does it mean for us?</strong></td>
<td>You will have to decide whether to continue or end the pregnancy. You will be supported to make this difficult decision. If you definitely would not want to end your pregnancy, think carefully about the extra risks you take by having an amniocentesis test.</td>
</tr>
<tr>
<td><strong>What are women told after an amniocentesis?</strong></td>
<td>1) Most women will be told that their baby does not have Down syndrome. 2) A small number of women will be told that their baby has Down syndrome. 3) An even smaller number of women will be told that their baby does not have Down syndrome, but does have another chromosome problem.</td>
</tr>
<tr>
<td><strong>Are there other tests?</strong></td>
<td>Does not apply</td>
</tr>
</tbody>
</table>

---

Editors: Marie-Anne Durand (Lead Editor), Benjamin Droppin, Peter Aff Collins, Bryan Beestle, Glyn Elwyn.

Editors have declared no conflict of interest.

Publication date: 2016-05-15
ISBN: 978-0-9550573-3-3
License: CC BY-NC-ND 4.0 (International)

This Option Grid™ decision aid does not constitute medical advice, diagnosis, or treatment. See Terms of Use and Privacy Policy at www.optiongrid.com.

(Durand et al., 2017)
Example: Healthwise

Healthwise (Healthwise 2017)
- Nonprofit founded in 1975
- Merged with Informed Medical Decisions Foundation in 2014
- Develops PDAs and provides SDM consulting
- Proprietary, see terms of use

172 patient decision aids reported in OHRI PDA inventory (OHRI 2017)

Maternity aid certificated by WSHCA
- Pregnancy: Birth options if your baby is getting too big (WSHCA Shared 2017)
AHRQ

National program (AHRQ 2017)

See next presentation for detailed description
Efforts that are not SDM

There are a vast number of patient education projects and resources in the US.

Many are beneficial for patients, and some share similarities with shared decision making.

However, these resources:
  ◦ Often do not meet evidence-based recommendations for quality patient decision aids
  ◦ Sometimes have significant unintentional or intentional bias.

These materials are developed by:
  ◦ Research institutes, providers, payors, insurers, pharmaceutical companies, tech companies, medical device companies, patient advocacy groups, and many other organizations.
Barriers and Facilitators
International resources on SDM barriers and facilitators

Implementing shared decision making (Légaré F, Scholl I, Stacey Dawn, Turcotte S, 2016)


Twelve myths about shared decision making (Légaré F, Thompson-Leduc P 2014)

Shared decision-making and interprofessional collaboration in mental healthcare: a qualitative study exploring perceptions of barriers and facilitators (Chong W, Aslani P, Chen T, 2011)

AHRQ SHARE Approach (AHRQ 2017)
US health care
Barriers

Complexity

Health care spending $3.2 trillion, $9,990 person, 17.8% of GDP (CMS 2017)
  ◦ Fee-for-service give providers financial incentive increase utilization
  ◦ Payor and insurers have financial incentives for decreased utilization
  ◦ SDM and PDA projects are at risk for bias in either direction

Large number of new projects to improve health care
  ◦ Collaboration can be difficult even when people have shared goals.
  ◦ The number of new processes and initiatives can be overwhelming.
US health care

Facilitators

Policy has been shifting away from fee-for-service
  ◦ Toward incentives based on patient-centered outcomes
  ◦ Toward incentives for cross-organizational collaboration

Having a large and diverse group of stakeholders can bring
  ◦ Knowledge and experience from different fields
  ◦ Many perspectives on ways to solve problems

Quality criteria include disclosure of conflict of interest (IPDAS 2017, WSHCA 2017, NQF 2016)
Provider barriers

Cultural expectation that they should be authorities who know the answers

Concerns that SDM will take too much time (Légaré F, Thompson-Leduc P 2014)

Belief that providers are already doing SDM (Légaré F, Thompson-Leduc P 2014)

Need for training in SDM skills
Provider facilitators

More widespread training programs are now available.

Evidence that use of PDAs do not necessarily take more time. (Cochrane 2017)

Awareness that SDM can involve multiple health care team members, and does not need to occur within a single provider encounter.
Patient perspectives

Barriers

Expectation that providers are authorities who know the answers.

Concern that their doctor will not help them with the decision. (Légaré F, Thompson-Leduc P 2014)

Concern that bringing up their values and preferences will make the provider unhappy. (Légaré F, Thompson-Leduc P 2014)
Patient perspectives
Facilitators

Outreach programs, such as AHRQ’s 3 questions (AHRQ 2017)

Broader approaches for collaborating with patients to advance quality SDM: Examples

- Patient Centered Outcomes Research Institute (PCORI 2017)
- The Patient Revolution, working with KER Institute at Mayo Clinic (Patient Revolution 2017)
SDM, PDA costs, uncertainty

Barriers

Longer term processes for developing and maintaining evidence-based, unbiased SDM and PDA resources.

Challenges in identifying the best ways to measure SDM quality.

SDM research and pilots rarely include a representative sample of the overall US population.
SDM, PDA advances

Facilitators

Learning from international expertise, sharing of knowledge and resources

Funding for advancing SDM development

Ongoing research on how to measure SDM quality (Bouniols, Leclère, Moret 2016)

Ongoing research on combining patient and provider interventions to improve SDM.

As more providers and patients in underserved populations are included in SDM research and implementation, we will gain new perspectives on ways to advance quality in SDM.
Conclusion
Conclusion

Thanks to organizations in the US and worldwide, we have:

◦ Broader awareness of SDM
◦ Deeper, evidence-based understanding of quality in SDM
◦ More policy and funding to support SDM in practice
◦ Growing inclusion of patients in efforts to improve SDM.

Work remains

◦ Defining high-quality SDM
◦ Determining the most effective ways to implement SDM
◦ Establishing fair access to high-quality SDM for patients nationwide.
25 Years Ago

“Ethically valid consent is a process of shared decisionmaking based upon mutual respect and participation, not a ritual to be equated with reciting the contents of a form that details the risks of particular treatments.”

(President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1982)
Today

We cannot define and implement perfect shared decision making.

But we can **improve** the current decision making process.

And we should.
Thank you
References

- King J, Moulton B. Group Health’s participation in a shared decision-making demonstration yielded lessons, such as role of culture change. Health Aff. 2013.
References (continued)

Questions