Curi® ADVISORY

PROTECT. OPTIMIZE. GROW. LEARN.

Searching for Efficiencies? Risk Management Considerations with AI Scribes Today

September 27, 2024

Donna Nicholson, MBA, BSN, RN, CPCO

Disclaimer

The information in this presentation is not intended as, does not constitute, and should not be relied upon as, legal, accounting, or tax advice.

Any information provided by Curi in this presentation is the property of Curi and protected by copyright.

If you download, record, and/or otherwise utilize the information in this presentation, you agree not to display, distribute, license, publish, reproduce, duplicate, copy, create derivative works form, modify, sell, resell, transfer or upload for any commercial purposes, all or any portion of these materials for any purpose unless explicitly authorized by Curi.

Disclaimer

Curi's risk mitigation resources and guidance are offered for educational and informational purposes only. This information is not medical or legal advice, does not replace independent professional judgment, does not constitute an endorsement of any kind, should not be deemed authoritative, and does not establish a standard of care in clinical settings or in courts of law. If you need legal advice, you should consult your independent/corporate counsel. We have found that using risk mitigation efforts can reduce malpractice risk; however, we do not make any guarantees that following these risk recommendations will prevent a complaint, claim, or suit from occurring, or mitigate the outcome(s) associated with any of them.

Any information provided by Curi in this presentation is the property of Curi and protected by copyright.

If you download, record, and/or otherwise utilize the information in this presentation, you agree not to display, distribute, license, publish, reproduce, duplicate, copy, create derivative works from, modify, sell, resell, transfer, or upload for any commercial purposes, all or any portion of these materials for any purpose unless explicitly authorized by Curi.

Agenda

1. Artificial Intelligence in Healthcare

2. AI Scribe Implementaiton – Risk Considerations

3. Artificial Intelligence Adoption and Governance in your Practice

4. Summary

Curi. ADVISORY

Considerations

1. Benefits of AI Use in Healthcare

2. Risks of AI Use in Healthcare

3. Potential Malpractice Allegations for using AI or *Not Using* AI

4. Using AI for Clinical Decision-Making

5. Considerations for Transition into AI Use

Curi. ADVISORY

Considerations

1. Benefits of AI Use in Healthcare
   - Improved diagnosis with AI analysis of images for disease detection
   - Medication dosage error reduction
   - Optimizing TX regimens based on patient profile
   - Administrative workflow efficiencies such as scheduling and **AI Scribes**
   - Continuity of care and improved clinical operations

Considerations

2. Risks of AI Use in Healthcare

- **Wrong or inaccurate data input will create inaccurate output**
- Clinician's may **"rubber-stamp" AI input** (e.g. **AI Scribe**-generated encounter note) without recognizing the AI has generated false information leading to medical malpractice exposure
- Racial and ethnic bias in training databases
- Data and cyber breaches
- Patient concerns about transparency and privacy
- Lack of Knowledge, policies, and accountability for errors
- Lack of regulatory clarity regarding who owns the output for the AI tool – patients, vendor, or clinician?
- Use of AI may become the **standard of care** in certain states or for certain treatments and some clinicians may not be able to afford such AI tools

Curi. ADVISORY

Considerations

3. Potential Malpractice Allegations for using AI or *Not Using* AI

   - Delayed DX and failure to DX

   - Surgical TX Errors

   - Improper Medical TX or delay in TX

   - Improper patient monitoring

Curi. ADVISORY

Considerations

4. Using AI for Clinical Decision-Making
   - What if the AI tool yields the wrong information? Who is responsible?
     - AMA position, court results, etc.
   - Documentation
     - Patient Consent
     - Disagreement with AI tool

Considerations

5. Considerations for Transition into AI Use
    - Do not use free tools such as ChatGPT – though your patients might!
    - Demo the tool and request a trial period
    - Complete your Due Diligence not only on functionality but also related to legal terms, contract review, existing EMR vendor consequences
    - Consider using a patient consent form for AI Scribe utilization

Curi. ADVISORY

Artificial Intelligence and Scribes

Curi. ADVISORY

Checklist

1. Identify Practice Requirements
2. Research Vendors
3. Verify HIPAA Compliance
4. Business Associate Agreement
5. AI Scribe Training
6. Integration AI Scribe Software
7. Trial Run
8. Communicate Expectations and Enforce New Processes
9. Monitor Performance
10. Patient Communication

Checklist

1. **Identify Practice Requirements**
    - Determine Tasks where AI scribes would be most beneficial
        - Patient Intake
        - H&P
        - Encounter notes
        - Other

Checklist

2. **Research Vendors**

- Establish a multi-disciplinary team to investigate AI scribe software companies, starting with your own EMR vendor and review of your vendor contract
    - Are they US based or Off-shore?
    - Explain what happens with down time – reliability
    - Security protections, HIPAA, cyber liability insurance coverage?
    - Customer or HelpDesk support should there be issues?
    - Software restrictions on certain note formats, like SOAP note style or other?
    - To what extent can the software be customized?

- Assess accuracy of the tool, EMR integration, Cost, ease of use

- Choose wisely!

Curi® ADVISORY

Checklist

3. Verify HIPAA Compliance

- HIPAA Compliance is required of vendor

- Does software have end-to-end encryption and meets all industry standards?

- If AI scribe software records conversations, be sure to obtain patients' written consent before recording

- Software should be HITRUST certified to include controls that appropriately protect the privacy and security of health care data

4. Business Associate Agreement (BAA)

- Read with meaningful attention – considering indemnification obligations and limitation on liability

- Do not consent in the BAA to the use of PHI to train AI tools

Curi. ADVISORY

Checklist

5. AI Scribe Training

- Thorough SOPs and Polices and procedures – multi-disciplined team

- All team members must have AI Scribe education with verification

- AI Hallucinations or Inaccuracies – what do you do?

- Expect to see that humans are liable for negative outcomes. AI Scribing is a tool not a decision maker

- All notes MUST BE REVIEWED and validated for accuracy

The Federation of State Medical Boards...

"Failure to apply human judgment to any output of AI is a violation of a physician's professional duties."

Checklist

6. **Integration of the AI Scribe Software**

7. **Trial Run**

- Request the necessary length of time to demo the AI software and recruit testers!

- Monitor and document testing comments, outcomes, accuracy, etc.

- Ensure all of your questions are answered

8. **Communicate Expectations and Enforce New Processes**

- Review P&Ps SOPs Compliance requirements and expectations, potential disciplinary actions

- Roles and responsibilities of all team members – do not allow role creep

- Who is overseeing the process?

- Who is assuring safety?

Curi. ADVISORY

Checklist

9. Monitor Performance

- Obtain feedback from users

- Implement quality assurance measures to mitigate risks associated with AI-generated documentation

- Assume there will be AI hallucinations

- Assure all AI generated entries are validated by the responsible party

10. Patient Communication

- Sign an Informed Consent

- Assure you have provisions for documentation should the patient decline

Curi. ADVISORY

Use of Artificial Intelligence (AI) Scribe During Medical Encounters Patient Authorization

Patient name _____

Facility name _____

Facts about an AI Scribe

Our medical office is using a new AI scribe technology. This tool helps us during patient medical encounters by making clinical notes or other records based on our talks with patients. The AI tool does not interact with you. It listens to and records the conversations and makes a draft clinical note. Your doctor will then review, edit, and finalize the clinical note. Using this tool lets us focus more on you, the patient, and less on computer records.

Risks and Common Problems

There are risks linked to the use of AI, which include but are not limited to:

Language capabilities: AI scribe technology right now works only with English-speaking patients. There may be some errors in translation for those with limited English skills.

Breakdown of the AI tool: This could stop or slow your evaluation or treatment.

Security safeguards: If there is a breakdown in the tool's security safeguards, this could result in your health data being made available to other people.

Other Choices

Your participation is fully your choice. If you do not agree to the use of this AI tool during your visit, it will not be used. If you change your mind about the use of this tool in the future, you may withdraw at any time by telling your doctor and we will not use the AI tool at or after that visit unless you later decide you wish to use the tool.

I confirm by signing below that:

- I have been able to ask questions about the use of AI during my medical encounters.
- No guarantees have been made about the use of AI.
- All of my questions have been answered.
- I agree to the use of the AI tool based on the terms noted above.

~~Signature of Participant or Responsible Party~~   ~~Date and Time~~

~~Relationship to Participant (if Responsible Party is not Participant)~~

© 2024 Curi. All rights reserved.

_____   _____

Physician Signature   Date and Time

American Medical Association (AMA)

- Artificial Intelligence – Scribes

  o Enhances Human Intelligence rather than replacing it

  o Reduces the burden of documentation within and outside of direct patient encounters

  o Enhance the physician-patient relationship

  o Improves patient engagement by increasing the amount of time clinicians can interact with patients instead of a computer during the visit.

Patient Care

Quality Requirements
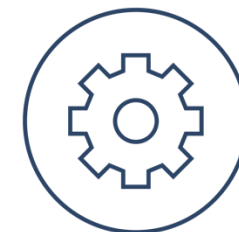
Functionality

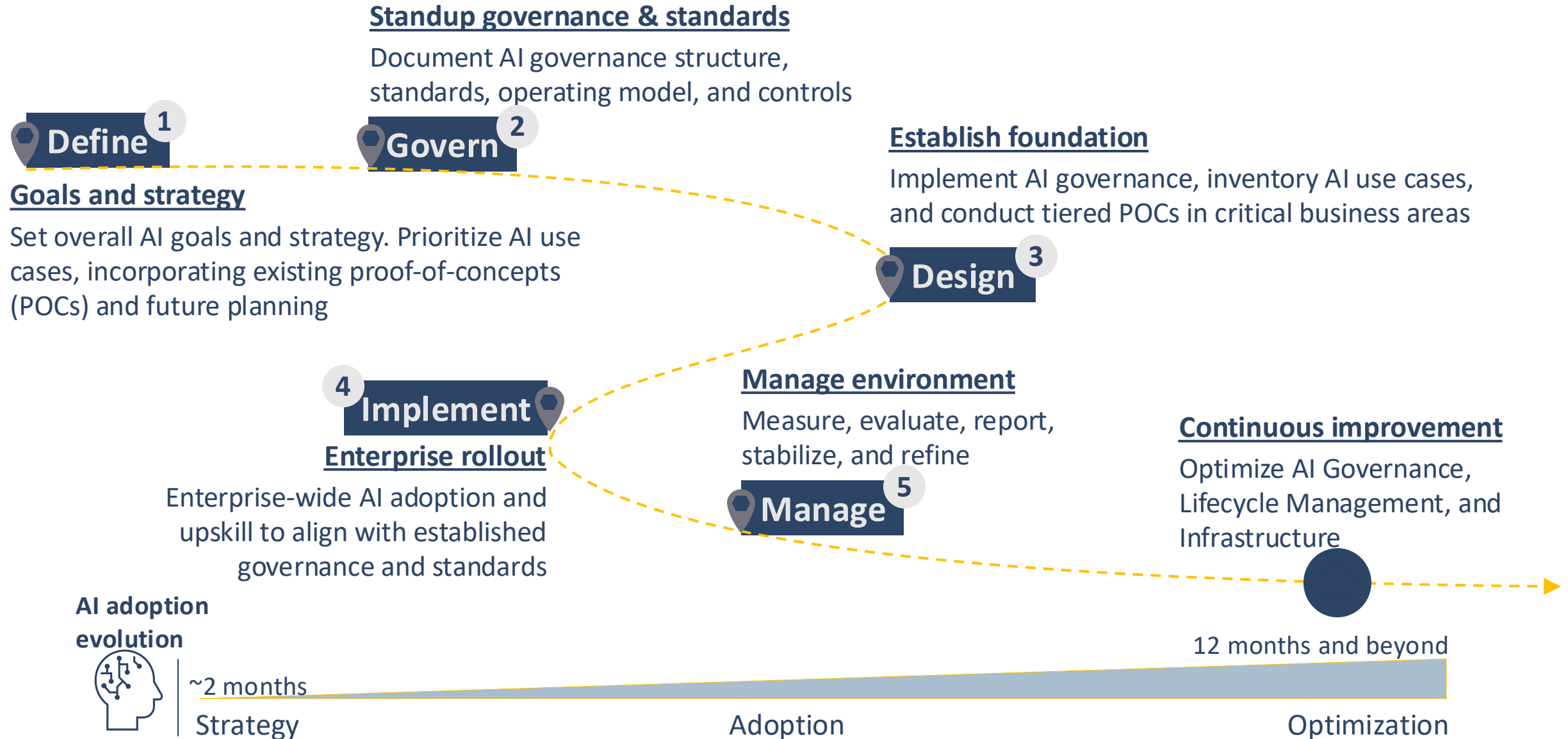# AI Governance & Enterprise Implementation Framework

Overview – Keep It Simple

PROTECT. OPTIMIZE. GROW. LEARN.

/jamesnicholsoniv

Artificial Intelligence Adoption and Implementation Journey

Many organizations are exploring how their artificial intelligence journey should begin...5-step approach

Standup governance & standards

Document AI governance structure, standards, operating model, and controls

Define 1

Govern 2

Establish foundation

Implement AI governance, inventory AI use cases, and conduct tiered POCs in critical business areas

Goals and strategy

Set overall AI goals and strategy. Prioritize AI use cases, incorporating existing proof-of-concepts (POCs) and future planning

Design 3

4 **Implement**

Manage environment

Measure, evaluate, report, stabilize, and refine

Enterprise rollout

Enterprise-wide AI adoption and upskill to align with established governance and standards

5 **Manage**

Continuous improvement

Optimize AI Governance, Lifecycle Management, and Infrastructure

AI adoption evolution

~2 months

12 months and beyond

Strategy

Adoption

Optimization

Summary

- Does your EMR offer AI scribing software – if so or if not and you choose a third-party vendor. Does that violate your EMR contract?

- Assure generative AI versus recording

- Assure generous trial period

- Assure optimal planning, governance, training and quality controls

- Secure SOP for patient consent

- HIPAA Security and Privacy requirements

- Design and implement your AI Governance Structure!!

Governance

Trusted Vendor

Quality Assurance

Curi. ADVISORY

Thank you!

Donna Nicholson

Managing Director, Curi Risk Solutions

Donna.Nicholson@curi.com

Curi. ADVISORY