

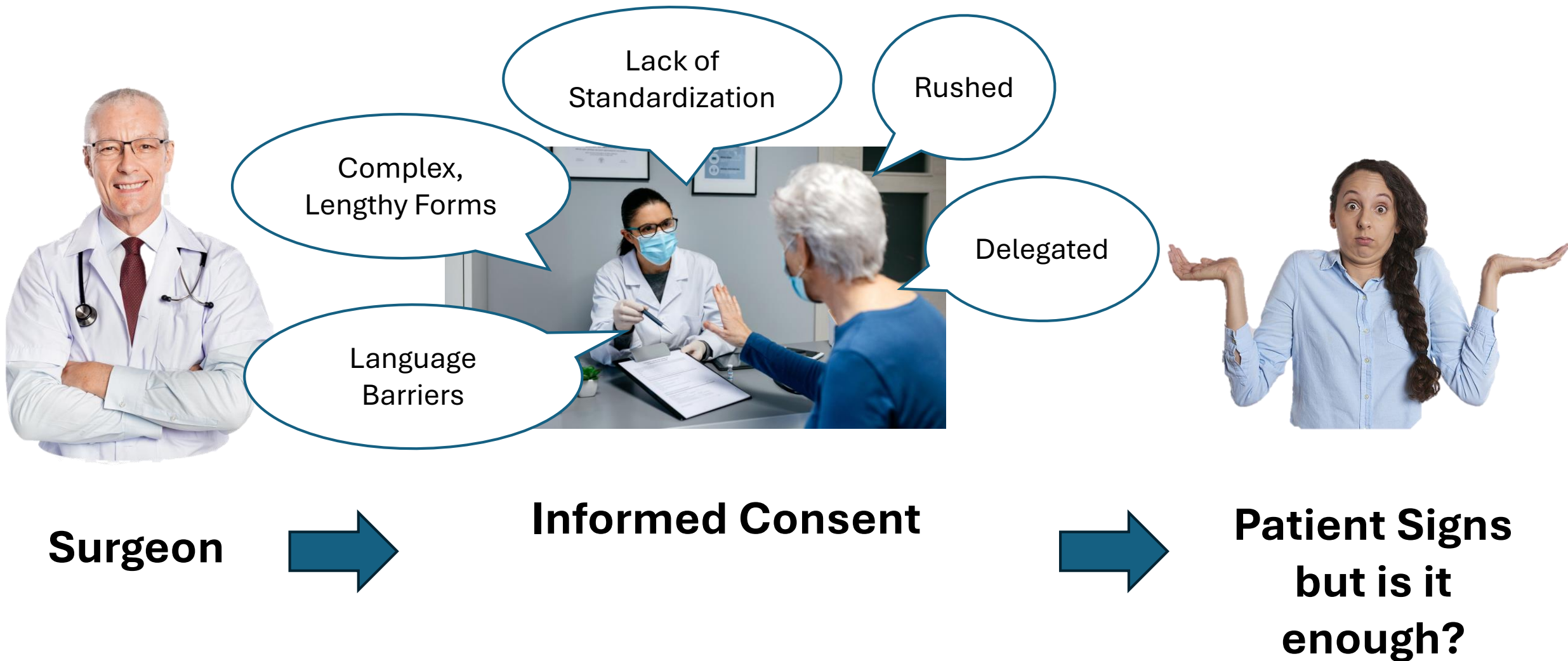
Consent-GPT: the Evolving Role AI-Companions in Informed Consent

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What does the current informed consent process look like for most patients?



Issues with current consent process: **overemphasis on legal protection** and **limited focus on patient understanding and satisfaction**

- **70%** of patients feel the time spent on consent is inadequate
- **50-60%** of patients find consent forms too lengthy and complex
- **45%** of patients feel the person obtaining consent lacks sufficient understanding
- **40%** of patients feel fully informed after the consent process
- **20-30%** of medicolegal claims cite inadequate consent as a factor



*References at end of talk

What does AI-delegated consent look like in 2025?

- Automatically AI-generated consent forms
- AI Chatbots to guide consent dialogue
- AI generated videos or images
- AI-powered translation
- AI-powered interactive consent systems with in-built quizzes



Example:
Prompt 1 =
create a consent
form for
removing an
inclusion cyst



produce a consent form for removing an inclusion cyst



Creating a consent form for the removal of an inclusion cyst involves covering several key points to ensure that the patient is well informed about the procedure, its benefits, risks, and any potential complications. Here's a basic template that you might find useful:

PATIENT CONSENT FORM FOR REMOVAL OF INCLUSION CYST

Patient Information:

- Name:
- Date of Birth:
- Patient ID:

Procedure Information:

- Procedure: Removal of Inclusion Cyst
- Date of Procedure:
- Surgeon:

Description of the Procedure: This procedure involves the surgical removal of an inclusion cyst, which is a non-cancerous cyst typically found under the skin. The cyst and its contents will be excised, and the area will be sutured.

Purpose of the Procedure: The purpose of this procedure is to remove the inclusion cyst to prevent infection, relieve pain, and improve cosmetic appearance.

Benefits of the Procedure:

- Relief from discomfort or pain caused by the cyst.
- Reduced risk of infection.
- Improved cosmetic appearance of the affected area.

Risks and Possible Complications:

- Infection at the site of the surgery.
- Scarring or changes in skin color.
- Recurrence of the cyst.
- Bleeding or hematoma formation.
- Allergic reactions to anesthesia.

Alternatives to the Procedure: The patient may choose to not have the cyst removed, accepting the potential for growth, pain, or other symptoms to continue or worsen.

Post-Procedure Care: Instructions on care will be provided, which may include:

Prompt 2= Create an Arabic version that complies with Kuwait's 2020 Law



For a consent form that adheres to the specific legal requirements set forth by Kuwait's Agency for Medical Responsibility and incorporating elements from the 2020 law, it will be essential to include clauses that address the responsibilities of healthcare providers, patient rights, and informed consent in detail. I'll draft an Arabic version of the consent form tailored to these requirements:

نموذج موافقة المريض لإزالة الكيس الدهني

معلومات المريض

- الاسم:
- تاريخ الولادة:
- رقم المريض:

معلومات الإجراء

- الإجراء: إزالة الكيس الدهني
- تاريخ الإجراء:
- الجراح:

وصف الإجراء: هذا الإجراء يتضمن الاستئصال الجراحي لكيس دهني غير سرطاني يقع تحت الجلد. سيتم استئصال الكيس ومحتوياته وخياطة المنطقة المعنية.

غرض الإجراء: الغرض من هذا الإجراء هو إزالة الكيس الدهني لمنع العدوى، وتخفيف الألم، وتحسين المظهر التجميلي.

فوائد الإجراء

- التخفيف من الانزعاج أو الألم الناتج عن الكيس.
- تقليل خطر العدوى.
- تحسين المظهر التجميلي للمنطقة المتأثرة.

المخاطر والمضاعفات المحتملة

- العدوى في موقع الجراحة.
- تندب أو تغيرات في لون الجلد.
- عودة ظهور الكيس.
- النزيف أو تكون الورم الدموي.
- الحساسية تجاه التخدير.

Prompt 3 = Make it funny

Consent Form for the Great Cyst Escape

Patient Information:

- Name: [First Class Passenger]
- Date of Birth: [Time Travel Credentials]
- Patient ID: [Secret Agent Code]

Mission Brief (Procedure Information):

- Mission: Operation Cyst Vanish
- Scheduled Date: [D-Day]
- Commanding Officer (Surgeon): [Dr. Who?]

Mission Details (Description of the Procedure): Your mission, should you choose to accept it, involves the strategic removal of a sneaky intruder known as an inclusion cyst. Think of it as a tiny unwanted squatter under your skin, not paying rent and occasionally throwing parties that cause discomfort. Our elite surgical team will infiltrate the area, evict the cyst, and clean up the mess with stitches.

Mission Objective (Purpose of the Procedure):

- **Primary Goal:** Kick the cyst out to prevent it from inviting more troublesome friends like infection and pain.
- **Secondary Goal:** Improve the landscape of your skin, enhancing its visual appeal.

Perks of Success (Benefits of the Procedure):

- Bid farewell to discomfort or pain caused by the cyst's wild parties.
- Decrease the likelihood of an infection rave.
- Beautify the neighborhood (the affected skin area).

Risks and Unforeseen Events (Possible Complications):

- A surprise guest (infection) might crash at the site.
- Possible graffiti (scarring) or change in district color (skin color changes).
- The cyst might be a boomerang and come back to party again.
- Potential for unexpected plot twists (bleeding or hematoma).
- Reaction to the anesthesia could be a real party pooper.

Alternate Plot Lines (Alternatives to the Procedure): Let the cyst continue its residency,

Example: Adapt it for a 6 year old

Superhero Consent Form for the "Bye-Bye Bumpy" Adventure

Superhero Identity:

- Name: [Your Superhero Name]
- Birthday: [When You Started Your Hero Journey]
- Hero ID: [Your Top-Secret Code]

Adventure Details:

- Adventure Name: Operation "Bye-Bye Bumpy"
- Adventure Day: [The Big Day]
- Hero Guide (Surgeon): [Your Favorite Superhero's Friend, Dr. Smiley]

What's Going to Happen? (Description of the Procedure): Imagine you have a tiny little rock under your skin that shouldn't be there. It's like a pebble in your shoe, but it's under your skin—annoying, right? Dr. Smiley and their team of hero helpers are going to gently remove that pesky pebble so you can go back to running and playing without any ouchies.

Why Are We Doing This? (Purpose of the Procedure):

- **Main Reason:** To take out the tiny rock so it doesn't bother you anymore.
- **Super Bonus:** Your skin will be super smooth for superhero costumes!

Super Powers You'll Gain (Benefits of the Procedure):

- No more annoying poke when you're having fun.
- Super-smooth skin at the secret rock spot.
- Be even faster and happier in your superhero adventures!

Oopsies That Might Happen (Possible Complications):

- A little boo-boo (infection) might happen at the spot, but we'll make sure to watch it closely.
- You might see a tiny hero mark (scar) where the rock was.
- Sometimes the rock tries to sneak back, but we'll be ready!

Other Adventures (Alternatives to the Procedure): You could leave the rock there, but it might poke you more as you do your awesome flips and jumps.

After the Adventure (Post-Procedure Care): Dr. Smiley will give you a superhero care map that shows:

Other potential prompts to customize the consent ...

- Create a picture to illustrate this procedure
- Explain this procedure at a 4th Grade level
- I am scared - please reassure me
- Provide me with exact statistics for each complication

Benefits of AI-Generated Consent Forms

- **Standardization** : reduce risk of omitting crucial information
- **Customization**: tailor to patient's literacy/preferences
- **Efficiency**: instant creation and dynamic updates
- **Accessibility**: different languages and formats (audio/video)
- **Education/Clarity**: incorporate diagrams, details
- **Record Keeping**: conversation can be kept in patient file

How does AI-assisted/delegated informed consent compare to traditional consent in current literature?

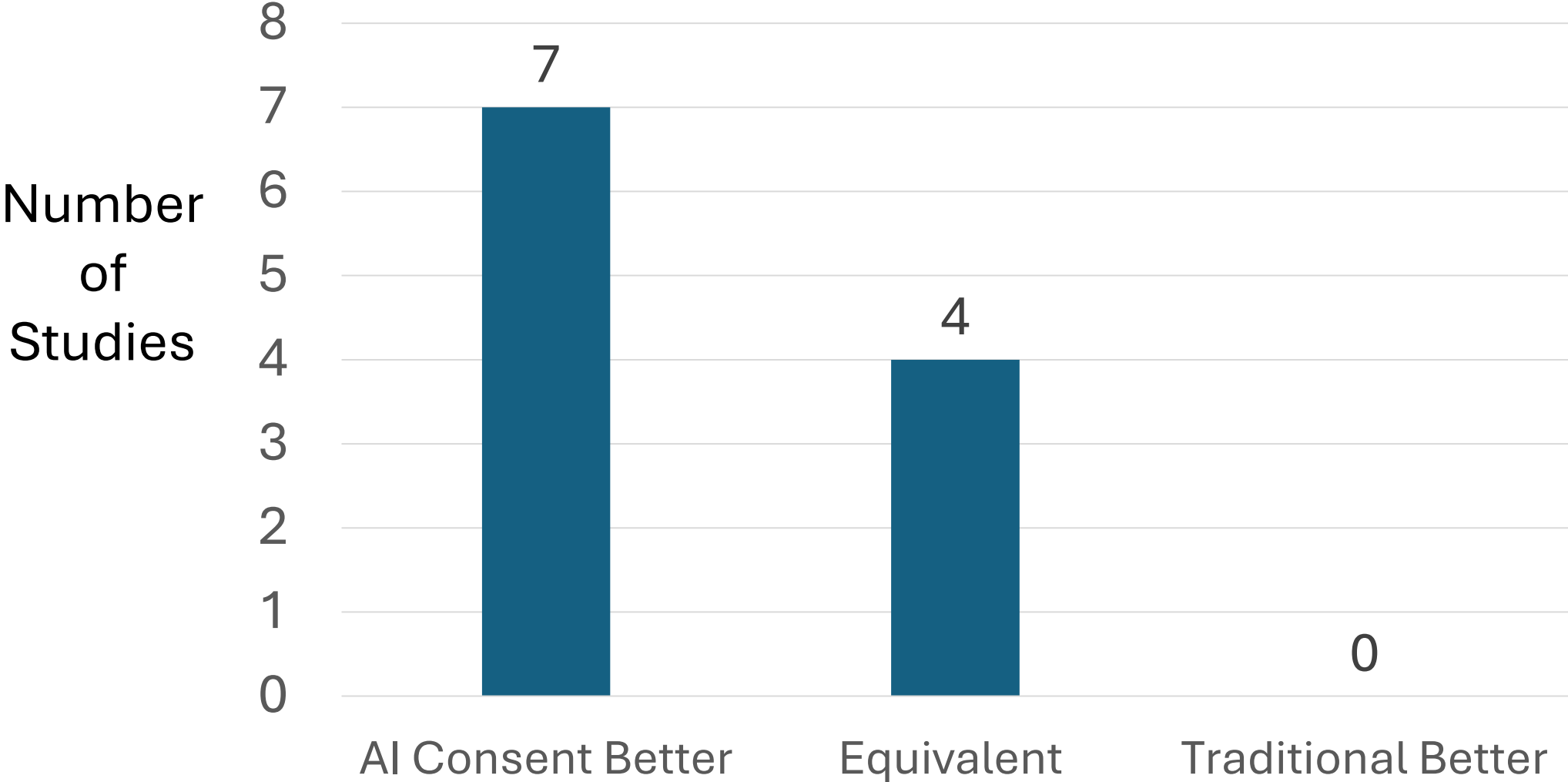
Systematic Literature Review: AI-driven Consent in Healthcare: Comparing Outcomes of Recall, Understanding, and Satisfaction

- Database Search: PubMed, Embase, Web of Science, CINAHL
- 2738 Studies Extracted → Screened & Filtered
- Exclusion Criteria:
 - Removed qualitative studies & opinion pieces
 - Must explicitly discuss AI-driven informed consent
 - Must measure recall, understanding, or satisfaction
 - Only English, human studies included
 - Excluded theoretical AI models without real-world testing
- **Final Inclusion: 11 Studies focusing on Recall, Understanding, and Satisfaction**

Summary of Included Studies

Study (Author & Year)	Number of Participants	Intervention Type	Outcome Measured	AI vs Traditional Consent	Quality Rating (GRADE)
Xiao et al. (2023)	238	AI Chatbot	Recall	AI Superior	High
Ali et al. (2024)	200	AI-Human Collaboration	Understanding	AI Superior	Moderate
Raimann et al. (2024)	180	AI Chatbot	Understanding	AI Equivalent	Moderate
Decker et al. (2023)	220	Large Language Model (LLM)	Understanding & Recall	AI Superior	High
Mirza et al. (2024)	175	AI-Assisted Readability Model	Satisfaction	AI Superior	Moderate
Grünebaum et al. (2024)	165	AI Chatbot	Understanding	AI Equivalent	High
Teasdale et al. (2024)	210	AI-Generated Forms	Understanding	AI Superior	Moderate
Vaira et al. (2024)	170	Generative AI	Recall	AI Superior	Moderate
Schmidt et al. (2024)	250	ChatGPT	Understanding	AI Equivalent	Low
Beattie et al. (2024)	190	AI-Enhanced Surgical Consent	Satisfaction	AI Superior	Low
Davis et al. (2024)	225	AI for Health Literacy	Satisfaction	AI Equivalent	Moderate

AI-assisted Consent Superior for Patient Recall, Understanding and Satisfaction Compared to Traditional Consent According to Most Studies



Literature Summary

- Limited studies demonstrate superiority of AI-driven consent
- Lack of high-quality literature evaluating AI-driven consent versus traditional consent

Challenges in Implementing AI-Driven Consent

- **Ethical** : legal uncertainty, data privacy, lack of human interaction (empathy, capacity assessment), bias
- **Technical** : accuracy and dealing with AI hallucinations, integration issues, language and cultural nuances
- **Legal and Regulatory** : lack of standardization and regulations for AI-driven consent
- **Adoption**: cost and infrastructure, physician and patient acceptance, digital literacy requirements

Solutions to AI-Driven Consent Challenges: Ethical and Regulatory Governance

- Develop AI-specific regulations and ethics standards with clear legal framework and transparency policies
- Define AI standards of care for medical consent including risk disclosure and require audits and clinical validation
- Collaboration Opportunity: Use Delphi process to develop guidelines, standards and regulations for local and global adoption

Reducing AI Errors: The Role of Custom GPTs

- Custom GPTs are AI models that are tailored for specific tasks, no-coding required
- Over 159,000 models now on OpenAI's GPT store, mostly free
- Use of pre-verified medical data minimizes hallucinations and ensures evidence-based recommendations
- AI can proactively gather patient preferences to personalize discussions, shifting the focus from mere consent to education and empowerment
- **Collaboration Opportunity: Develop a custom GPT that is accurate and perform validation testing**



Optimizing Arabic LLMs for Effective Adoption in Healthcare

- Current AI models are primarily trained in English and struggle with Arabic dialects and medical terminology
- Less than 1% of AI assistants use primary Arabic data, relying on translations that dilute meaning
- Arabic AI models like Jais and AceGPT lack multimodal capabilities and are trained on translated, not native Arabic
- **Collaboration Opportunity:** Just as Sakhr revolutionized Arabic computing, KFAS can lead in Arabic AI by curating and verifying medical datasets to build high-quality Arabic AI dataset with dialect-specific labeling to enhance accuracy beyond Modern Standard Arabic



Training Patients and Providers in AI and Digital Literacy for Better Adoption

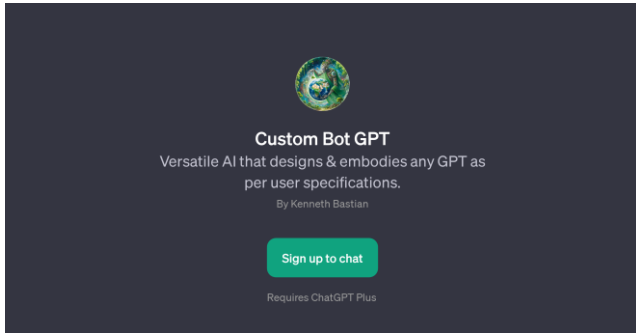
- New tools require new skills
- Equip patients and providers with essential digital literacy skills
- Teach clinicians how to use AI effectively, including crafting accurate prompts and how to validate information
- Guide patients on AI's benefits and limitations
- **Collaboration Opportunity: Develop educational programs for clinicians and patients on effective AI use, prompt crafting and information validation**



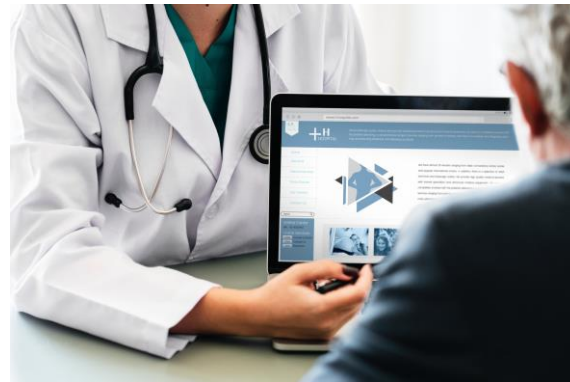
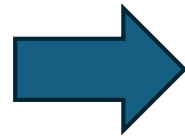
From Hesitation to Integration

- Shift focus from ***‘Should we use AI to obtain consent?’*** to ***‘How can we integrate AI to enhance patient consent process?’***
- Move beyond **permission-based consent** to an **educational** patient empowering process
- Develop AI –assisted, clinician-led clinical workflows, ensuring human validations at critical decision points and integrate into EHR

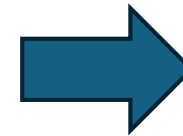
Proposed Method to Integrate AI into Clinical Workflows Whilst Incorporating Human Oversight



Clinicians checks capacity and help patient complete preferences prompts in validated Custom GPT



Patient goes through custom GPT either alone or with assistance by reading the output and typing answers to questions generated by custom GPT



Clinician verifies patient understood consent and prints chat history for inclusion in patient's file

The Future of Informed Consent: AI as a Partner Not Replacement

- **From a Legal Obligation to Patient Empowerment:** AI shifts consent from a checklist to a dynamic educational process
- **Strengthening Governance & Ethics:** Establish local and global standards, legal frameworks, and ethical AI guidelines
- **Enhancing Accuracy and Standardization:** AI-driven tools are ideal for standardizing information, personalizing education and improving patient recall
- **Integrating AI into Workflows:** AI-assisted, clinician-led models ensure human oversight into key decision points whilst leveraging AI benefits
- **Bridging Language and Literacy Gaps:** Arabic-specific solution to enhance accessibility and cultural acceptance
- **Building Trust and Enhancing Adoption:** Digital literacy training to equip providers and patients for proper use

References

- Schenker, Y., et al. (2011). *Medical Decision Making*, 31(1), 151-171. [DOI: 10.1177/0272989X10364247]
- Akkad, A., et al. (2006). *BMJ*, 333(7567), 528. [DOI: 10.1136/bmj.38922.516204.55]
- Lavelle-Jones, C., et al. (1993). *BMJ*, 306(6882), 885-890. [DOI: 10.1136/bmj.306.6882.885]
- Bismark, M. M., et al. (2006). *The New England Journal of Medicine*, 355(7), 626-631. [DOI: 10.1056/NEJMsa052049]
- Falagas, M. E., et al. (2008). *BMC Medical Ethics*, 9(1), 17. [DOI: 10.1186/1472-6939-9-17]
- Kinnersley, P., et al. (2013). *Cochrane Database of Systematic Reviews*, (6), CD004565. [DOI: 10.1002/14651858.CD004565.pub3]
- Studdert, D. M., et al. (2006). *The New England Journal of Medicine*, 354(19), 2024-2033. [DOI: 10.1056/NEJMsa054479]