





Unmet needs in the Clinical Setting in the era of Al and CDSS

This technology will solve unmet needs and definitively change the way medicine is practiced, and medical knowledge is managed



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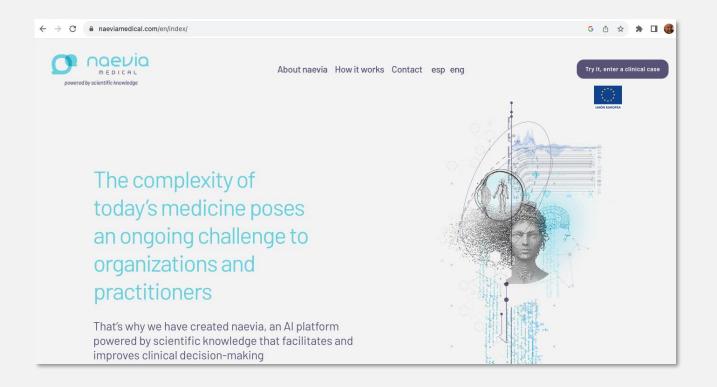






Conflicts of interest Co-founder











1/3 Unmet needs in the Clinical Setting





Decision support

Ensuring the quality of Clinical Decisions

- Bridging the gap between scientific evidence and medical practice through better **adherence to scientific recommendations**
- Underuse vs. overuse
- Avoiding preventable medical errors
- Reducing variability

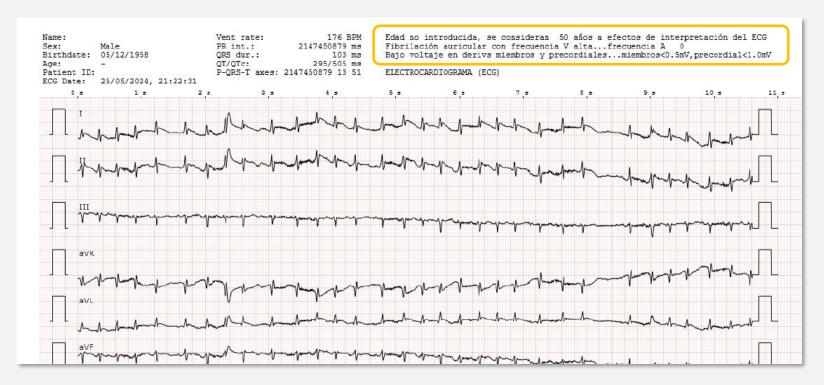






First generation CDSS Isolated interpretation of the finding







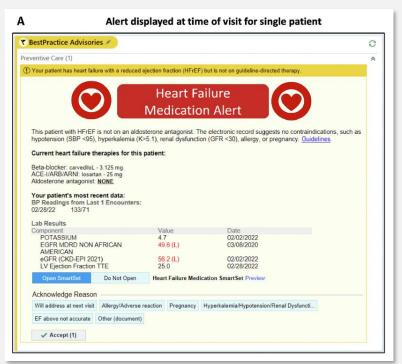




First generation CDSS



Systems designed to assist in a single decision



Ej. aldosterone antagonist

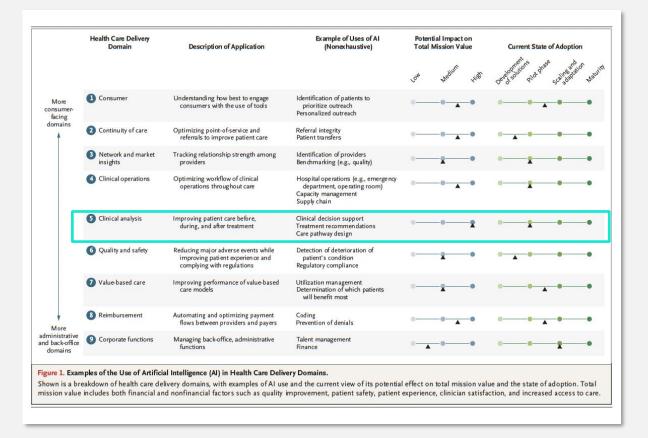






CDSS is the most impactful application of Al











2/3 Unmet needs in the Clinical Setting





Data and information management

- Remove the chaos of unstructured information in EHR
- Facilitate interoperable structuring at origin
- Facilitating access to data and reporting (50% of our time)

Capture of relevant information







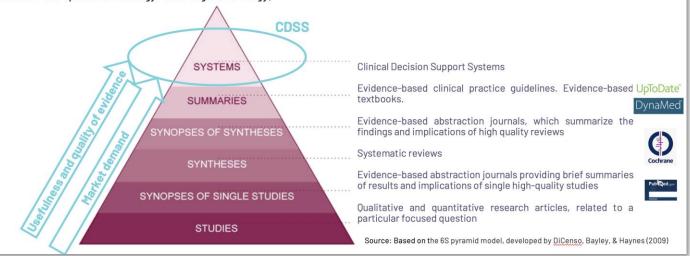
3/3 Unmet needs in the Clinical Setting





Medical Knowledge Management

"The growing patient demand for quality care has prompted healthcare systems worldwide to adopt CDSS technologies that help curtail costs, enhance care quality, prevent errors, and save time" (Source: Europe 2020 strategy. WHO digital strategy)



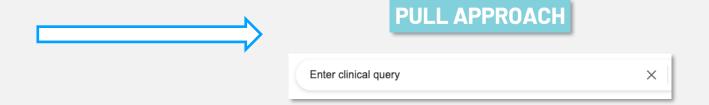






Traditional way. In case of doubt of knowledge





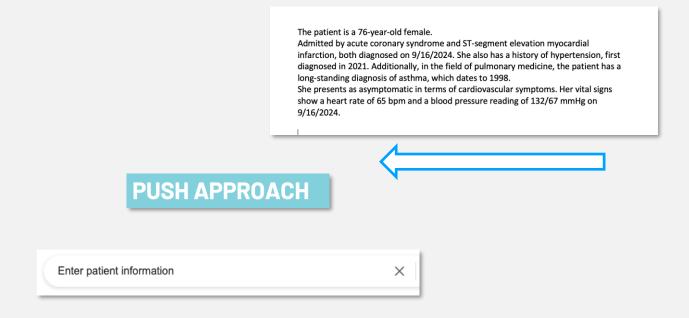






New model





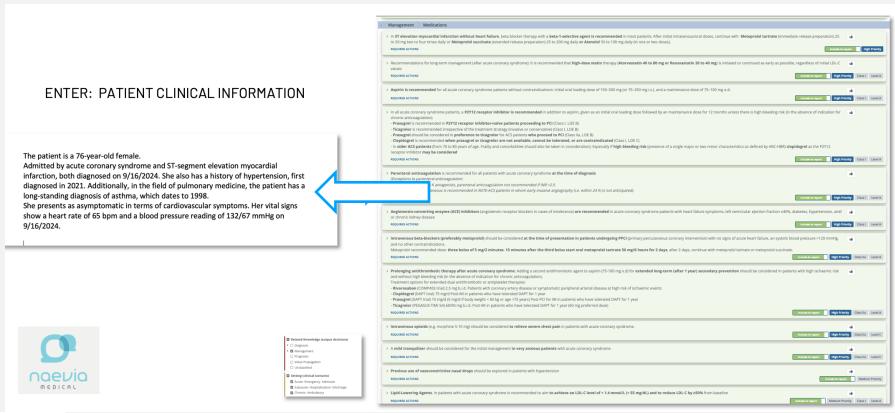






Recommendations that apply to patient characteristics





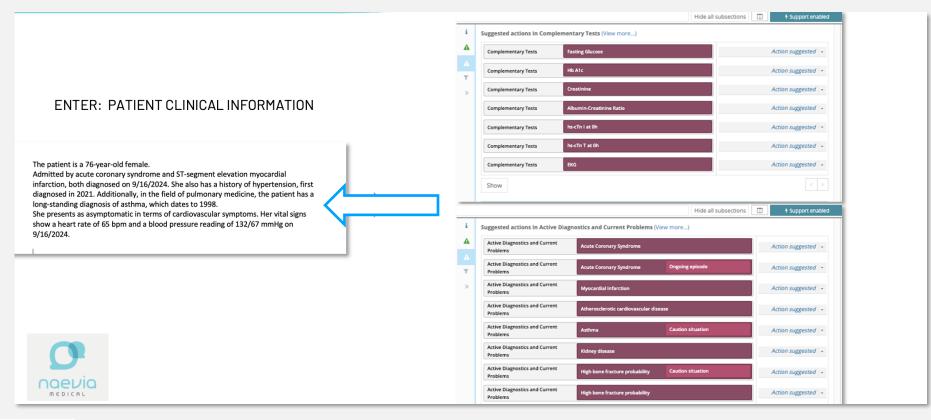






Identifying relevant missing information















 Knowledge-Based CDSS, automatic reasoning. Ruled based Al Applies clinical rules from a knowledge base



CDSS, Machine Learning
 Generative AI, Deep Neural Networks, Large Language Models (LLM)









Clinical Case



A 75-year-old man presented with an inferior myocardial infarction in February 2021, treated with primary angioplasty with stenting over the medial right coronary artery. Preserved systolic function. Affected by hypertension and type 2 diabetes. History of appendectomy.

He was treated with Acetylsalicylic acid 100 mgs, Atenolol 50 mgs, Atorvastatin 80 mgs and Omeprazole 20 mgs.

Asymptomatic.

Blood pressure 145/80 mmHg. 49 bpm.

Sinus rhythm

Glucose 157 mg/dL, HbA1c 7%, Creatinine 1.8 mg/dL, LDL cholesterol 67 mg/dL (1.74 mmol/L), HDL 35 mg/dL, Triglycerides 160 mg/dL /1.81 mmol/L).

Is this patient well treated, should I make any diagnostic or therapeutic decisions with him?







1. Rule based CDSS Inferences and diagnostic recommendations



A 75-year-old man presented with an inferior myocardial infarction in February 2021, treated with primary angioplasty with stenting over the medial right coronary artery. Preserved systolic function. Affected by hypertension and type 2 diabetes. History of appendectomy.

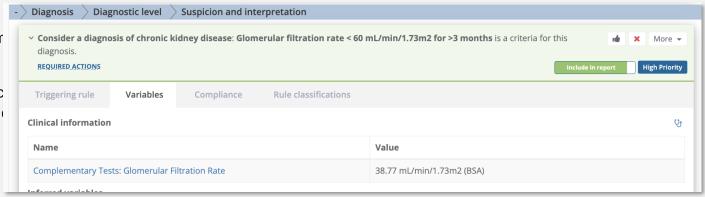
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Asymptomatic.

Blood pressure 145/80 mm

Sinus rhythm

Glucose 157 mg/dL, HbA1c mg/dL, HDL 35 mg/dL, Tri









1. Rule based CDSS. Test recommendations



A 75-yea February medial ri	 It is recommended that all patients with type 2 diabetes are screened for kidney disease by assessing eGFR (estimated glomerular filtration rate) and UACR (urinary albumin-to-creatinine ratio) at least annually, regardless of treatment REQUIRED ACTIONS Include in report Medium Priority Level B									
hyperten	Triggering rule	Variables	Compliance	Rule classifications						
He was Atorvasta	Clinical information									
Asympto	Name				Value					
,	Active Diagnostics a	and Current Probl	ems: Diabetes Mellit	us, Type 2	True					
Blood pre	Inferred variables									
Sinus rhy	Name				Value					
Glucose ' mg/dL, H	No data available in table									
	 ✓ Measurement of urine albumin:creatinine ratio is recommended in all patients with arterial hypertension. REQUIRED ACTIONS Include in report Medium Priority Class I Level B 									
	Triggering rule	Variables	Compliance	Rule classifications						
	Clinical information	n						Ç		
	Name				Value					
SC	Active Diagnostics a	and Current Probl	ems: Hypertension		True					







1. Rule based CDSS. Therapeutic recommendations



A 75-year-old I February 2021, medial right of hypertension a He was treate Atorvastatin 80 Asymptomatic Blood pressure Sinus rhythm Glucose 157 mg mg/dL, HDL 35

Y Angiotensin-converting enzyme (ACE) inhibitors (angiotensin receptor blockers in cases of intolerance) are recommended in acute coronary syndrome patients with heart failure symptoms, left ventricular ejection fraction ≤40%, diabetes, hypertension, and/ or chronic kidney disease REQUIRED ACTIONS **High Priority** Class I Level A Triggering rule Compliance Rule classifications Variables Clinical information Value Name Active Diagnostics and Current Problems: Acute Coronary Syndrome Verdadero Active Diagnostics and Current Problems: Diabetes Mellitus True Inferred variables Name Value No data available in table > In patients with type 2 diabetes with multiple atherosclerotic cardiovascular disease (ASCVD) risk factors or established ASCVD, sodiumglucose cotransporter-2 inhibitors (empagliflozin, canagliflozin, dapagliflozin, ertugliflozin, or sotagliflozin) are recommended to reduce the risk of heart failure hospitalization. **REQUIRED ACTIONS** High Priority Class I Level A > In patients with type 2 diabetes, tight glycaemic control (HbA1c < 7%) should be considered for reducing coronary artery disease in the long term, preferably using agents with proven cardiovascular benefit: sodium-glucose cotransporter-2 inhibitors (empagliflozin, canagliflozin, dapagliflozin, sotagliflozin) or glucagon-like peptide-1 receptor agonists (liraglutide, semaglutide s.c., dulaglutide, efpeglenatide). REQUIRED ACTIONS **High Priority** Include in report Class IIa Level B







1. Rule based CDSS. Therapeutic recommendations



A 75-year-old man presented with an inferior myocardial infarction in February 2021, treated with primary angioplasty with stenting over the

medial right cc hypertension at He was treate Atorvastatin 80 Asymptomatic. Blood pressure Sinus rhythm Glucose 157 mg mg/dL, HDL 35

 ✓ In patients with type 2 diabetes, finerenone is recommended <i>in addition to an angiotensin-converting enzyme inhibitor or angiotensin-II receptor blocker</i> in patients with: eGFR >60 mL/ min/1.73 m2 with a Albumin-Creatinine Ratio (UACR) ≥30 mg/mmol (≥300 mg/g), or eGFR 25-60 mL/min/1.73 m2 and UACR ≥3 mg/mmol (≥30 mg/g) to reduce cardiovascular events and kidney failure. REQUIRED ACTIONS 								
Triggering rule	Variables	Compliance Rule classifications						
Clinical information	Clinical information \heartsuit						Ų	
Name				Value				
Active Diagnostics and Current Problems: Diabetes Mellitus, Type 2			True					
Inferred variables								
Name				Value				
No data available in table								



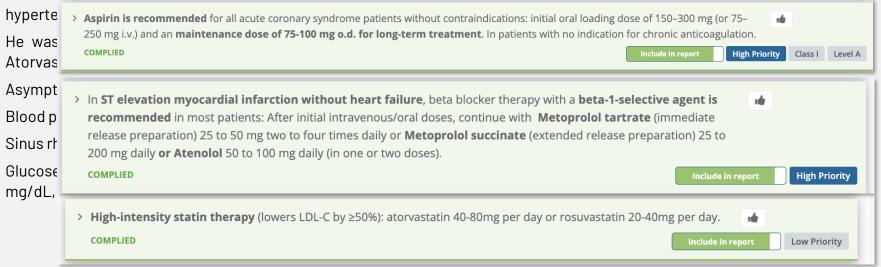




1. Rule based CDSS. Adherence to scientific recommendations



A 75-year-old man presented with an inferior myocardial infarction in February 2021, treated with primary angioplasty with stenting over the medial right coronary artery. Preserved systolic function. Affected by









1. Rule based CDSS. Lipid lowering recommendations



A 75-year-old man presented with an inferior myocardial infarction in February 2021, treated with primary angioplasty with stenting over the medial right coronary artery. Preserved systolic function. Affected by

1	from a mean action and alternative for the first and a						
İ	 Patients with diabetes have an individual target LDL-C accroding to thier associated cardiovascul statins, combination therapy with ezetimibe is recommended. 	lar risk. If this target is not reached with					
,	REQUIRED ACTIONS	Include in report High Priority Class I Level B					
-	> Recommendations for long-term management (after acute coronary syndrome): If the LDL-C goal statin therapy after 4–6 weeks, the addition of ezetimibe is recommended (the aim is to redu achieve LDL-C < 1.4 mmol/L (< 55 mg/ dL)						
(REQUIRED ACTIONS	Include in report High Priority Class I Level B					
	Recommendations for long term management (after acute coronary syndrome): If the LDL-C goal is not achieved after 4-6 weeks of maximally tolerated statin therapy and ezetimibe, the addition of a PCSK9 inhibitor is recommended. The aim is to reduce LDL-C by >=50% from baseline and to achieve LDL-C < 1.4 mmol/L (< 55 mg/ dL)						
L	REQUIRED ACTIONS	Include in report High Priority Class I Level B					







1. Rule based CDSS. Therapeutic recommendations



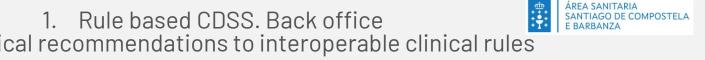
	✓ In patients with diabetes and dyslipidemia with associated hypertriglyceridaemia (i.e. triglycerides 150–499 mg/dL), high-dose icosapent ethyl (2 g bis in die) may be considered in combination with a statin							
A 75-year-old mar	REQUIRED ACTIONS Include in report High Priority Class Ila Level C							
February 2021, tre	Triggering rule	Variables	Compliance Rule classification	ons				
medial right coror hypertension and	Cililical information				৬			
	Name			Valu	Value			
He was treated v Atorvastatin 80 mg	Complementary Tests: Triglycerides				160 mg/dL			
Atorvastatinoonii	Current Medications: HMG-CoA reductase inhibitors				True			
Asymptomatic. Active Diagnostics and Current Problems: Diabetes Mellitus					True			
Blood pressure 14!	Inferred variables							
Sinus rhythm	Name				Value			
Glucose 157 mg/dl	No data available in table							
mg/dL, HDL 35 mg								
mg/dE, HbE 33 mg	✓ Icosapent ethyl, at a dose of 2 g b.i.d., can be used in combination with a statin in patients with ACS and triglyceride levels of 1.5-5.6 More ▼ mmol/L (135-499 mg/dL) despite statin treatment REQUIRED ACTIONS Medium Priority							
	Triggering rule	Variables	Compliance Rule classification	ons				
	6							
	Name				Value			
	Complementary Tests: Triglycerides				160 mg/dL			
SC	Active Diagnostics and Current Problems: Acute Coronary Syndrome				Verdadero			
INIVERSIDADE DE SANTIAGO DE COMPOSTELA	Current Medications: HMG-CoA reductase inhibitors				True			

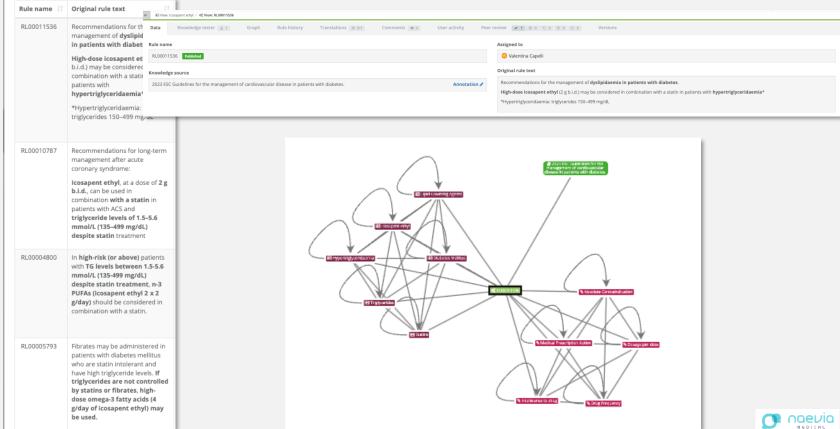






1. Rule based CDSS. Back office From medical recommendations to interoperable clinical rules





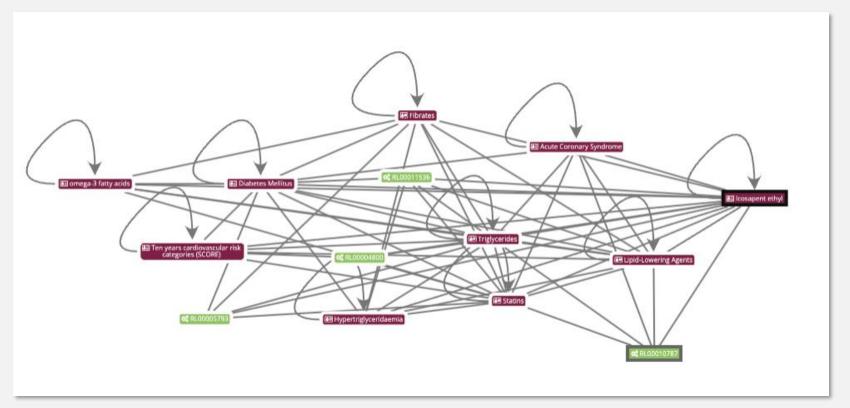






1. Rule based CDSS. Knowledge graphs











2. Generative Al



ChatGPT 4o ~

What can I help with?

What diagnostic and therapeutic recommendations apply to this patient. "A 75-year-old man presented with an inferior myocardial infarction in February 2021, treated with primary angioplasty with <u>stenting</u> over the medial right coronary artery. Preserved systolic function. Affected by hypertension and type 2 diabetes. History of appendectomy.

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Glucose 157 mg/dL, HbA1c 7%, Creatinine 1.8 mg/dL, LDL cholesterol 67 mg/dL, HDL 35 mg/dL,













2. Generative Al



Diagnostic Recommendations

1. Blood Pressure and Heart Rate Monitoring:

Regular home or ambulatory blood pressure and heart rate monitoring would help ensure
optimal blood pressure and heart rate control.

2. Glycemic Monitoring:

 Regular self-monitoring of blood glucose (SMBG) is important. In addition, periodic HbA1c tests should be conducted every 3–6 months to assess longer-term glycemic control.

3. Renal Function and Electrolytes:

 Monitor serum creatinine and electrolytes, particularly potassium, given the possible addition of an ACE inhibitor or ARB, which could impact renal function and electrolyte balance.

4. Lipid Profile:

 Regular lipid profiles (every 6–12 months) to monitor LDL, HDL, and triglycerides and assess cardiovascular risk status.

5. Cardiac Monitoring:

 Periodic ECGs to monitor for any arrhythmias, particularly if heart rate continues to be low.

6. Retinopathy and Neuropathy Screening:

 Annual eye exams and neuropathy assessments are recommended for diabetes management to detect early complications.

7. Lifestyle Recommendations:

Encourage a heart-healthy, diabetic-friendly diet, regular physical activity (tailored to his
capacity and limitations), and smoking cessation if applicable.

Therapeutic Recommendations

1. Blood Pressure Control:

- Although blood pressure is at an acceptable level (145/80 mmHg), target levels for patients with cardiovascular disease and diabetes are typically below 130/80 mmHg.
- Medication Adjustment: Atenolol (a beta-blocker) is useful post-MI, but consider adding
 or switching to an ACE inhibitor or ARB, given its additional benefit for cardiovascular risk
 reduction in diabetic patients.
- Suggested Goal: Target blood pressure of <130/80 mmHg.

2. Diabetes Management:

- Glucose Control: The patient's fasting glucose is elevated at 157 mg/dL, with an HbA1c of 7%. This indicates that glucose control needs improvement, especially given the history of MI and the added cardiovascular risk of diabetes.
- Medication: If not already on one, consider introducing an SGLT2 inhibitor or GLP-1
 receptor agonist, as these have proven cardiovascular benefits in diabetic patients.
 Continue to monitor HbA1c with a target closer to 6.5% if possible, balancing with the risk of hypoglycemia.

3. Lipid Management:

- LDL Cholesterol: Current LDL levels are within the target (<70 mg/dL for high-risk patients), so continuing atorvastatin at 80 mg seems appropriate.
- HDL and Triglycerides: The HDL is low at 35 mg/dL, and triglycerides are slightly
 elevated at 160 mg/dL. While statins don't impact HDL significantly, increasing physical
 activity and possibly dietary changes may help improve HDL.
- Consider: If triglycerides rise further, consider adding omega-3 fatty acids (EPA), especially for cardiovascular protection.

4. Antiplatelet Therapy:

 Aspirin: The patient is on acetylsalicylic acid (aspirin) 100 mg daily, which is standard post-angioplasty and should be continued.

5. Heart Rate Control:

 The current heart rate is 49 bpm, which is low, likely due to Atenolol. Assess for symptoms like dizziness or lightheadedness. If symptoms are present, consider reducing the atenolol dose or adjusting to a different beta-blocker with a shorter half-life.







2. We ask again



Diagnostic and Therapeutic Recommendations

Given this patient's history and recent lab results, here are the recommended diagnostic assessments and therapeutic adjustments:

Diagnostic Assessments

1. Renal Function Monitoring:

- The creatinine level (1.8 mg/dL) suggests the need to monitor kidney function more closely. Calculating the estimated glomerular filtration rate (eGFR) would provide a clearer picture of renal function.
- Regular follow-up tests for creatinine and eGFR are advised, especially since the patient is on medications such as atenolol and atorvastatin, which may impact kidney health.

2. Metabolic Control and Diabetes Evaluation:

- The fasting glucose (157 mg/dL) and HbA1c (7%) indicate suboptimal diabetes control. A
 full glucose profile might help to understand daily glucose variations and, if possible,
 continuous glucose monitoring (CGM) could be beneficial.
- The current diabetic regimen may need adjustment to improve glucose control, potentially adding or optimizing medication after assessing the current treatment plan.

3. Further Cardiovascular Evaluation:

- Although the patient is currently asymptomatic, a follow-up stress test or imaging (such
 as a stress echocardiogram or myocardial perfusion imaging) could be beneficial for
 monitoring coronary health, especially given the history of myocardial infarction.
- An echocardiogram can further evaluate ventricular function, even though he currently has preserved systolic function.

Therapeutic Recommendations

1. Blood Pressure Optimization:

- The patient's blood pressure is 145/80 mmHg, which is slightly above target levels for someone with cardiovascular disease and diabetes. Adjusting antihypertensive therapy could be beneficial to reach a target closer to 130/80 mmHg if tolerated.
- Atenolol can be continued, but an ACE inhibitor or ARB (angiotensin receptor blocker) might be considered to offer both renal and cardiovascular protective benefits, potentially substituting or adding to the current regimen.

2. Lipid Management:

- LDL cholesterol is well-controlled (67 mg/dL), likely due to atorvastatin 80 mg. However, HDL (35 mg/dL) and triglycerides (160 mg/dL) could be further optimized. Lifestyle modifications, such as dietary adjustments and physical activity, can help.
- If necessary, fenofibrate or omega-3 fatty acids could be considered, especially if triglyceride levels remain elevated.

3. Glycemic Control:

 Since HbA1c is above target, tighter glycemic control is needed. Assessing the current diabetes medication and considering an addition or adjustment (such as a GLP-1 receptor agonist or SGLT2 inhibitor) could improve glycemic control while providing cardiovascular benefits.

4. Medication Review:

- Evaluate the need for long-term omeprazole, given potential kidney impacts, especially in someone with borderline renal function.
- Aspirin and atorvastatin should continue as secondary prevention for cardiovascular disease. Regular monitoring of liver function and muscle symptoms with atorvastatin is also advised.

5. Lifestyle Modifications:

 Encourage a heart-healthy diet, regular physical activity, and smoking cessation if applicable. A diet rich in fiber, low in saturated fats, and moderate in carbohydrates can benefit both cardiovascular and diabetes management.







Limitations of LLMs in CDSS







to change the way we work and live, even as we must be aware

a bigger liability for patient care? With both the capabilities and
of substantial limitations of such systems in mind, we consider 3 levels of health





Requirements, strengths and weaknesses



• CDSS Requirements

Reliable and accurate. Based on verified information

Reproducible. Explainable. Validated

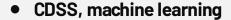
Integrated in the care process



Knowledge-Based CDSS, automatic reasoning

Require structured data (NLP)

Require programming and updating of scientific evidence



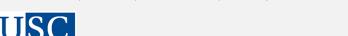
Require complex training and infrastructure

Biases of training bases, transparency and limitation of incorporation of new evidence.

Limited reliability. Hallucinations. Inaccuracies. Omission (reliable AI)

Explainability limitation (explanatory AI).





Al in medicine: creating a safe and equitable future. Lancet 2023 The future of health AMA 2024 Patient safety and artificial intelligence IHI 2024

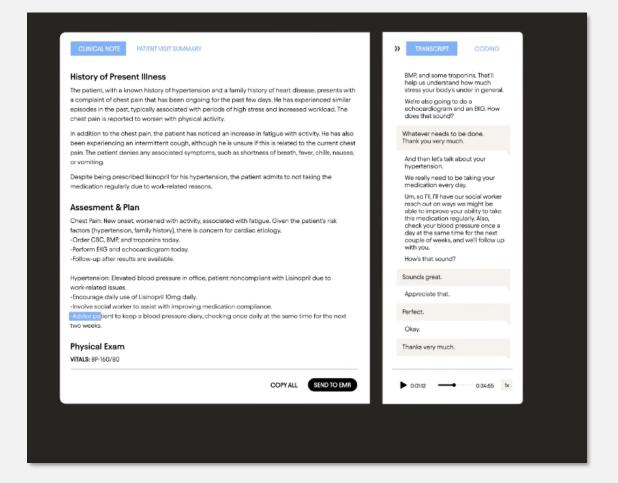




Other LLM application, structuring information































Complementarity of technologies



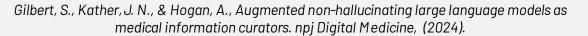






https://www.gartner.com/en/articles/when-not-to-use-generative-ai









Software as a medical device



Compared with What? Measuring AI against the Health Care We Have

Isaac S. Kohane, M.D., Ph.D.

whether I could recommend a pri- sachusetts General Hospital and mary care doctor. I assured my Brigham and Women's Hospital, colleague that I would promptly were turning away new patients. provide a set of excellent options I did not end up helping my new to choose from. When I reached colleague and instead suggested my contemporaries in medical company for recommendations. training, however, I learned that completely surprising, so I tried capita in the United States, which who were of more recent vintage a referral for primary care would and whom I'd encountered in a have been even more challenging cepting patients. Stunned, I wid- context, the possibility of aug- depleted system?

A recent faculty recruit in my ened my search further. I discovementing the work of clinicians department, an expert in are ered that primary care clinics at — including doctors, nurse prac-

N ENGL I MED 391:17 NEIM-ORG OCTOBER 31, 2024

tificial intelligence (AI), asked me some local hospitals, such as Mastitioners, and physician assistants - with AI is being seriously considered.2 Yet AI tools that could reduce burdens on clinicians are most likely the tip of the iceberg when it comes to Al's influence out to several doctors who were contacting their health insurance in medicine. Whether out of desperation, frustration, or curiosity, Massachusetts has among the large numbers of patients are althey had all retired. That was not highest number of doctors per ready using AI to obtain medical advice, including second opinanother tack: I contacted doctors suggests that an attempt to make ions — sometimes with dramatic therapeutic consequences.3 But individual anecdotes do not subsupervisory capacity. One of them in large swaths of the country. A stitute for systematic evaluation. cheerfully informed me that he recent report from the Associa- With any new clinical intervenwas no longer practicing primary tion of American Medical Coltion, rigorous trials are the medcare at a teaching hospital affiliat- leges on the physician workforce ical field's best tools to drive the ed with Harvard Medical School. makes it clear that this issue is establishment of best practices. When I asked him whether he unlikely to be resolved in the In the case of AI, shouldn't we could recommend any high-quality short term, and most evidence in be comparing health outcomes practices, his tone changed, and this area points to further wid- achieved with patients' use of he said that he couldn't think of ening of the workforce gap for these programs with outcomes in any such practices that were ac- primary care in the future. In this our current primary-care-doctorRecruiting 6 Validation of Naevia Medical in Valvulopathies (CDSS-Valve) ClinicalTrials.gov ID 1 NCT06392464 Sponsor Dilemma Solutions S.L. Information provided by 1 Dilemma Solutions S.L. (Responsible Party) Last Update Posted 1 2024-04-30

















This technology will solve unmet needs and definitively change the way medicine is practiced, and medical knowledge is managed

Thank you

Open for collaborations & partnership



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