

# HIMSS<sup>®</sup> 26

## EUROPE

19-21 May | Copenhagen

**Megan Coder, PharmD, MBA**

Vice President, Board of Directors  
Society for Digital Mental Health



**#HIMSS26EUROPE**

DISCLAIMER: The views and opinions expressed in this presentation are solely those of the author/presenter and do not necessarily represent any policy or position of HIMSS.

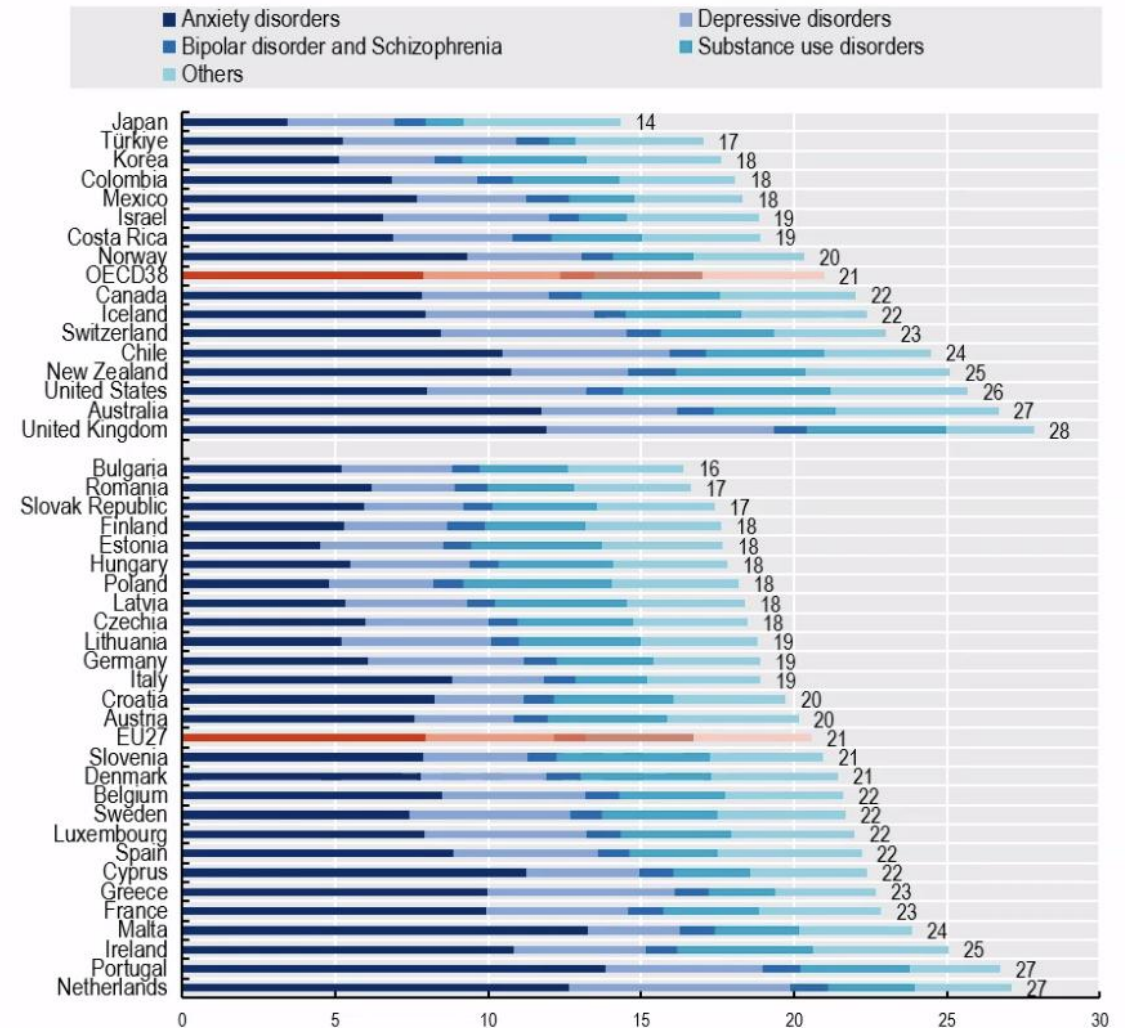
EXPERT **INSIGHTS**  
EXCEPTIONAL **IMPACT**



# Global mental health crisis

- **1 in 5 people** across OECD countries experienced a mental disorder in 2022
  - Depression, anxiety, and substance use disorders account for approximately  $\frac{3}{4}$  of all disorders
- But, many mild-to-moderate cases go undiagnosed due to stigma and system limitations, so the **true scale is unknown**
- **60%** of people who need mental healthcare **cannot access it** – versus only 3.8% unmet need for general medical care

Prevalence of mental disorders in EU and OECD countries

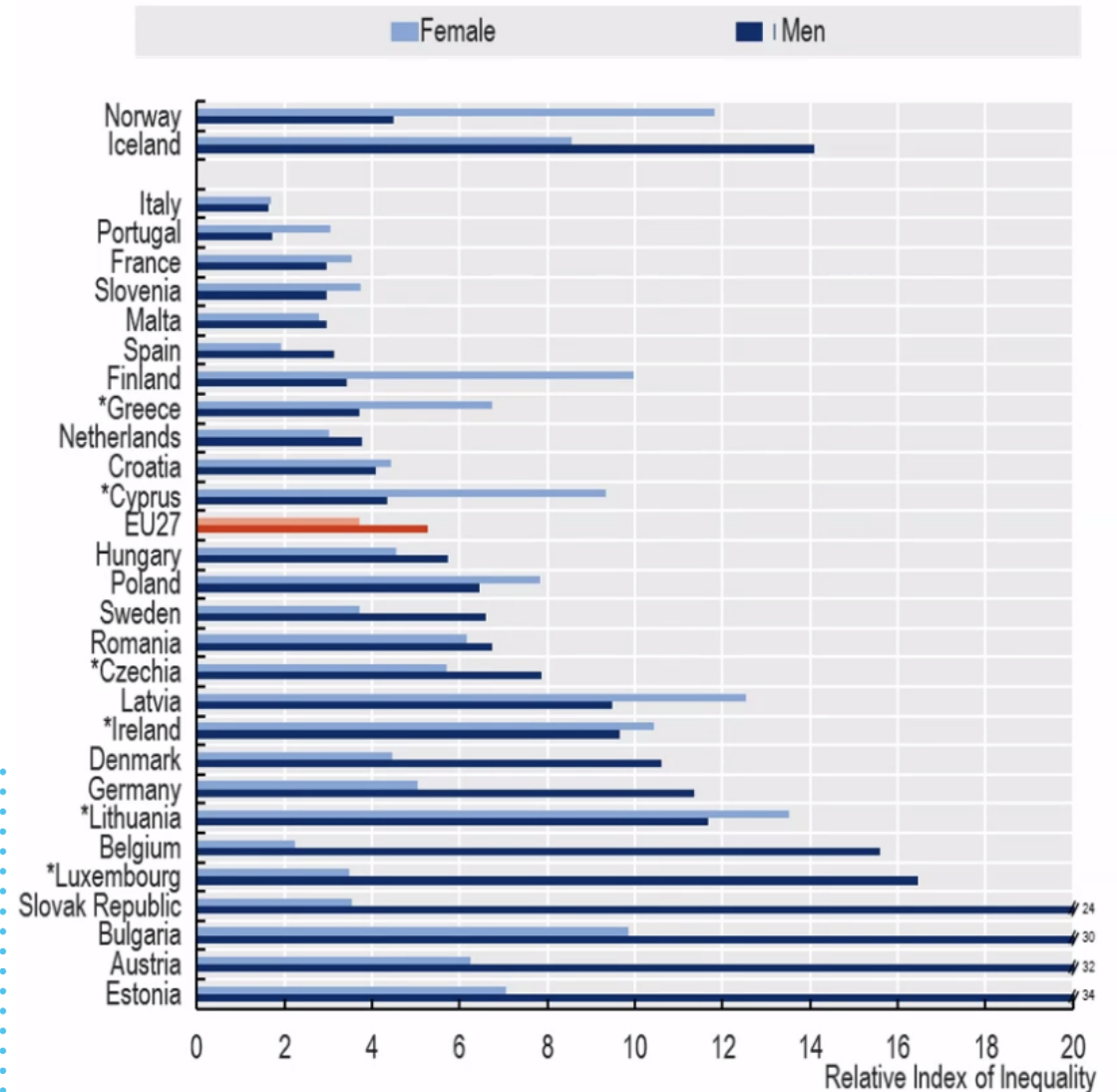


Source: OECD (2026), The Economic Case for Preventing Mental Ill Health, OECD Health Policy Studies, OECD Publishing, Paris, <https://doi.org/10.1787/16668f16-en>.

# Disproportionate impacts

- **Young people** are hardest hit – 1 in 4 individuals aged 15-24 currently experience a mental disorder, the highest of any age group
- **Gender** shapes the type of disorder – women report higher rates of anxiety and depression; men are more likely to experience alcohol and substance use disorders
- **Socio-economic status** is a strong predictor – lower income and education levels are consistently associated with higher rates of depression and anxiety

Income-related inequalities in depressive symptoms



Source: OECD (2026), The Economic Case for Preventing Mental Ill Health, OECD Health Policy Studies, OECD Publishing, Paris, <https://doi.org/10.1787/16668f16-en>.

## Gen Z loves AI...?

When asked why they used digital tools, nearly 70% said it felt more comfortable than speaking with someone directly, and half say digital tools were more affordable.

– Bipartisan Policy Center, 16 April 2026



## Gen Z hates AI...?

“Some Gen Zers – ages 14 to 29 – are ditching social media in pursuit of better mental health.”

– Axios, Rebecca Falconer, 7 May 2026

**...yet, AI is often becoming the default place people are turning to**

# Not all chatbots are the same

Note: The requirements qualify the label; not the other way around

## General-purpose LLMs

- Optimized for conversational fluency and engagement
- Not designed for clinical accuracy or patient safety
- No domain-specific training on mental health data
- No crisis escalation protocols
- No clinical validation or evidence base
- Widely accessible, with little to no regulatory oversight

vs.

## Purpose-built mental health AI

- Developed using domain-specific clinical data
- Built with clinical expertise and safety-oriented design
- Clear boundaries around appropriate use
- Crisis detection and escalation protocols
- Empirically validated against evidence-based standards
- Subject to regulatory scrutiny and evidence requirements

# General-purpose LLMs: playing pretend vs. validated care

*“Conversational fluency should not be mistaken for clinical accuracy or reliability. LLMs generate responses based on statistical patterns in data, without inherent grounding in clinical meaning, patient safety, or therapeutic boundaries.”*

Society for Digital Mental Health

## False sense of trust

Confident, empathetic AI responses can mask incomplete or misleading guidance – making it harder for patients to recognize when advice is unsound.

## Delayed treatment

When AI tools substitute for effective interventions or provide false reassurance, the indirect costs to patient outcomes can be as consequential as direct harm.

## No accountability

Unlike clinicians, LLMs are not bound by validated clinical frameworks, diagnostic criteria, licensure, or professional accountability structures.

# Recent lawsuits

**Garcia v. Character Technologies** | Filed: October 2024 | Florida | Settled

Sewell Setzer III, 14, died by suicide after months of interactions with a chatbot that engaged in sexual role-play and claimed to be a licensed therapist. Character.AI and Google agreed to settle in January 2026.

**Raine v. OpenAI** | Filed: August 2025 | California | Ongoing

Adam Raine, 16, died by suicide after ChatGPT allegedly encouraged his mental decline, discouraged him from confiding in his parents, and offered to write his suicide note.

**Peralta v. Character Technologies** | Filed: September 2025 | Colorado | Ongoing

Juliana Peralta, 13, died by suicide in November 2023 after allegedly depending on a chatbot called "Hero" that deepened her isolation rather than directing her to crisis resources.

**Shamblin v. OpenAI** | Filed: November 2025 | California | Ongoing

Zane Shamblin, 24, died by suicide after ChatGPT allegedly responded with affirmations over four and a half hours as he described his plans, writing "I'm not here to stop you."

# Who is liable when something goes wrong?

## The developer/vendor

*Did the product fail to perform as marketed?*

If a general-purpose LLM is not marketed as a clinical tool, the vendor may face limited exposure – even if users rely on it therapeutically.

*Verdict:* Often protected

## The deploying institution

*Did the hospital or health system choose to implement it?*

If a hospital deploys an AI tool – even a general-purpose one – in a care pathway, liability may shift to the institution. The boundaries are untested in court.

*Verdict:* Exposure uncertain

## The clinician

*Did the AI assist in a clinical decision?*

If AI output influences a clinical decision, professional liability may attach to the clinician – regardless of whether the AI was FDA-cleared or not.

*Verdict:* Potentially exposed

# Purpose-built mental health AI

## Conversational AI in Mental Health Market Map

The Hemingway Report

### Scaled Hybrid Platforms



### Clinical Infrastructure



### Consumer-First



# Regulatory landscape: A split screen

## United States

- **Direction:** Deregulatory
- **Jan 2026:** FDA Commissioner Makary: FDA needs to "get out of the way as a regulator"
- **Action:** Expanded enforcement discretion for digital health tools; withdrew international SaMD guidance
- **GenAI status:** No GenAI mental health device has been cleared. Low-risk tools largely exempt from oversight
- **Result:** Faster path to market; less evidence required



## Europe & UK

- **Direction:** Increasing scrutiny on purpose-built health AI tools
- **EU AI Act:** GPAI rules in force Aug 2025; full enforcement and fines from Aug 2026. ChatGPT has until 2027 for full compliance
- **UK MHRA:** National Commission on AI in Healthcare launched Dec 2025; AI Airlock regulatory sandbox funded through 2029
- **GenAI status:** Purpose-built tools face classification uncertainty; general models often slip through product safety gaps
- **Result:** Higher burden for compliant tools; general models face delayed enforcement



**Many products have historically operated within regulatory gray zones by positioning themselves as wellness applications rather than clinical tools.**

Society for Digital Mental Health

### General-purpose LLMs

- Not marketed as clinical tools – largely exempt
- No clinical validation required or expected
- Remain freely accessible regardless of use
- Face no meaningful enforcement today

### Purpose-built mental health AI

- Navigate regulatory classification uncertainty
- Invest in clinical validation and safety testing
- Face market withdrawal over ambiguous guidance
- Bear the cost of doing the “right thing”

# Case study: Ash by Slingshot

## **What Ash is:**

- Purpose-built foundation model trained on behavioral health data
- Trained across CBT, DBT, ACT, psychodynamic therapy and motivational interviewing

## **Timeline:**

- Ash entered the UK market *July 2025*, following an 18-month development and beta testing period
- Ash initiated a wind-down phase and withdrew from UK market in *January 2026*

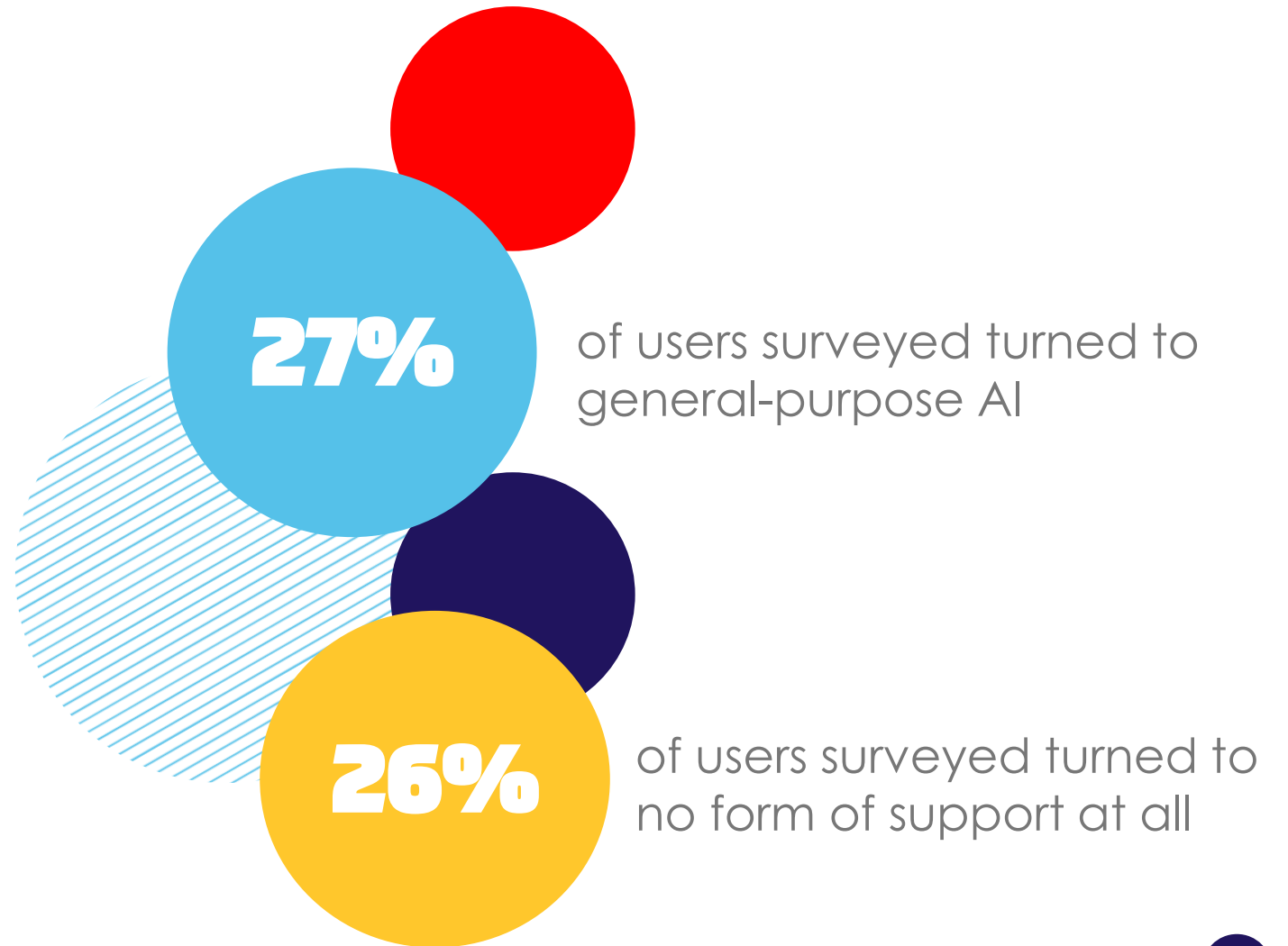
## **What happened:**

- Regulatory ambiguity ... not a safety failure
- Company spent months in dialogue with regulators before withdrawing
- CEO to users: "There isn't a clear regulatory pathway for wellbeing products like ours – and without that clarity, we can't operate with confidence"

# Ash: What was the outcome?

Once Ash – a purpose-built tool – was removed from the market, users largely did not transition their care to a therapist.

Instead, they turned to general-purpose AI tools ... or back to silence.





**We are not replacing therapists. We are providing a purpose-built alternative to the reality many consumers face when it comes to mental health support, which is ChatGPT – or nothing.**

Caitlin Stamatis, PhD | Head of Research, Slingshot AI

**Clarity around boundary conditions for these technologies is sorely lacking and regulatory pressure is being applied in the wrong places.**

Derrick Hull, PhD | Clinical R&D, Slingshot AI

HIMSS<sup>®</sup> 26  
EUROPE

Thank you

