

Building a Safer Future:

A Framework for Enhancing Patient Safety in Digital Mental Health Startups Across Europe

The dilemma

The rise of online e-mental health companies in Europe has outpaced regulation and guidance, especially for startups operating outside public healthcare systems. These companies often lack a structured approach to patient safety from the outset, instead choosing to focus primarily on GDPR and data security, sometimes confusing these areas with clinical patient safety. **A technology or a product, no matter how advanced, is not a complete healthcare service.** This gap in safety infrastructure can affect the quality of care and ultimately financial and commercial sustainability.

AI and LLMs offer exciting possibilities for e-mental health but we are still transitioning from exploratory ideas to established clinical and safety practices. Startups need a practical framework to build a patient safety infrastructure, even with limited resources.

To address this, Mindler's Global Clinical Governance team partnered with Verita to develop a **Patient Safety Framework for Digital Mental Health Startups**. Mindler operates digital mental health services in five European markets, and Verita specialises in healthcare consultancy and patient safety investigations.

Our goal

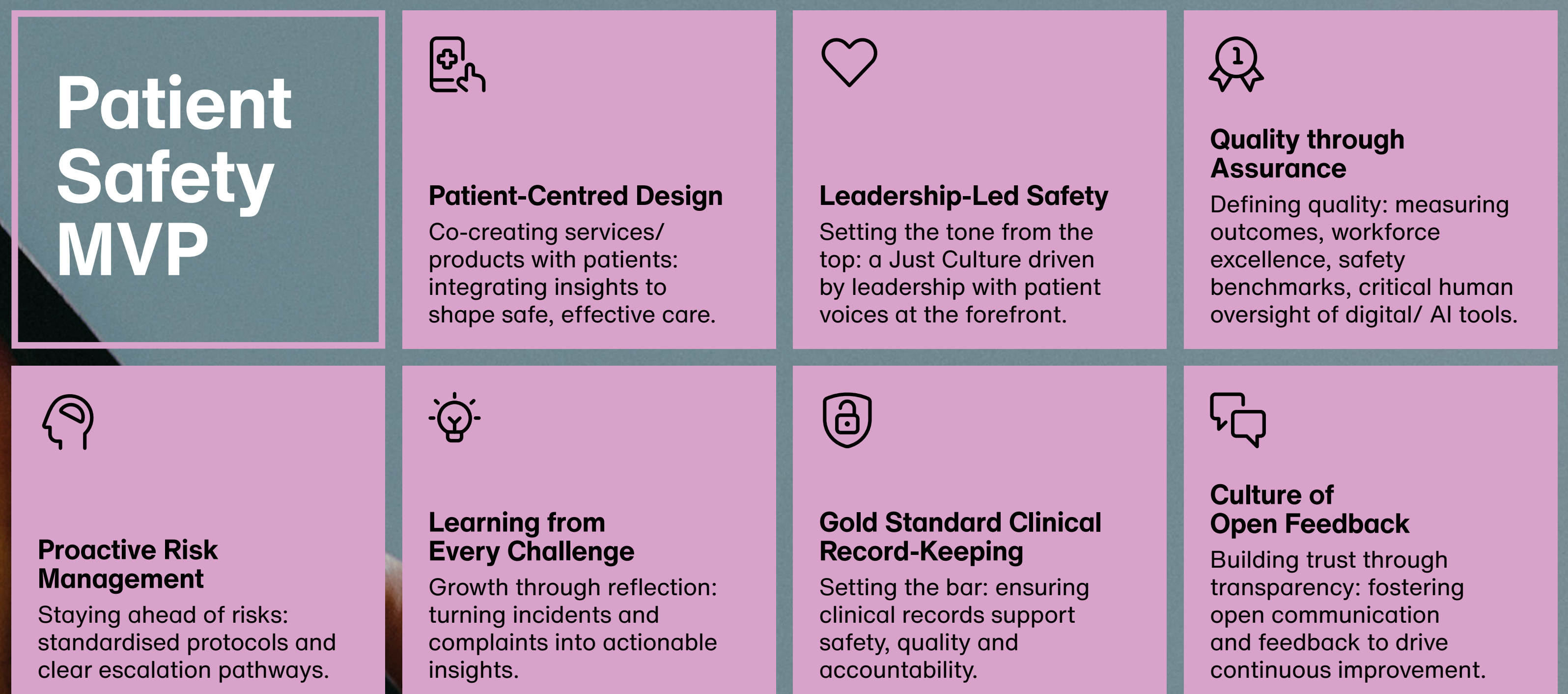
To create a **practical framework** to guide digital start-ups in embedding **patient safety from the start**.

Our Framework development method

- Literature reviews & policy analysis (e.g. WHO & European healthcare standards).
- Consultation with e-health leaders.
- Review of established models (e.g. Blueprint for Action, 2019).
- Live working documents & digital discussions.
- Reflections on our own professional experience

The framework

This tool helps startups plan services and assess safety maturity. It identifies seven key areas (see diagram) that form the foundation for a minimum viable patient safety product.



Measuring success

The framework encourages startups to set their own benchmarks, especially when baseline data is unavailable. It is designed for easy implementation during service design and allows adaptation as the fields of safety and AI evolve.

Critical questions that can be asked when implementing the framework are:

- How will we know this is working?
- How will we check?
- What evidence will we need?
- What would the patient think about this?

For example, key benchmarks and/or measures startups can use include:

- Patient feedback.
- Incident reporting quality.
- Safety focussed cross-departmental collaboration
- Use of incident investigations and implementation of recommendations.
- Safety discussions having a systemic learning focus rather than blame.
- Real-world effectiveness of AI implementation (e.g. false positive or false negative rates, adherence to established clinical guidelines).

Practical Considerations:

- A licensed clinician should lead the implementation of the framework.
- Safety must be embedded in business plans, budgets, and investor pitches. Safe care isn't just ethical - it's essential for financial and commercial success.
- The patient, not the tech or product, must always be at the center of safety design.
- Any AI implementation must include clearly defined human oversight to maintain quality and trust.

Conclusion

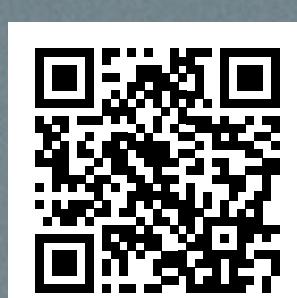
The framework helps leaders understand what to resource and implement, offering an easy and effective safety strategy for startups.

Early adoption = long-term success.

Safe care is fundamental to financial and commercial sustainability. Safety should be a core principle of any mental health service.

Read more and contact information

For more detailed information go to



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