Monitoring People with Depression in the Community: Regulatory Aspects

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Help4Mood is a system for supporting the treatment of people with depression in the community. Relevant aspects of the patient's condition are monitored; summaries and trends are shared with the clinician. In this paper, we describe how the decision to provide for integration into clinical practice has affected design and implementation of Help4Mood. We excluded useful functionality such as medication reminders and moved to a laptop as a secure platform.

Depression, Monitoring, Ethics, Medical Device, Risk Assessment.

1. INTRODUCTION

In Europe, most cases of depression are managed in the community (Tiemens et al, 1996). Questionnaires that are recommended for screening for and monitoring depressive symptoms in primary care, such as the PHQ-9 (Kroenke et al., 2001), require patients to estimate how they have been over the past two weeks, but these self-reports may be affected by the patient's current mood, their relationship with the health care practitioner they are seeing, or quite simply their memory.

Help4Mood is a light-touch monitoring solution that allows patients to track both subjective symptoms such as mood and negative thoughts and objective symptoms such as activity levels in their own home (Wolters et al, 2012). This information is distilled into a one-page summary that can serve as the basis for discussion between clinician and patient and inform further treatment. Figure 1 gives an overview of the system.

In Section 2, we discuss why this means that Help4Mood is classified as a Class I medical device. In Section 3, we outline the consequences that this classification has for system design and development and conclude in Section 4 with lessons learned for future developments.

2. HELP4MOOD IS A MEDICAL DEVICE

According to the Medical Device Directive 93/42/EC (2007 revision), a medical device is

> any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:
>
> — diagnosis, prevention, monitoring, treatmentor alleviation of disease,
>
> — diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap

> — investigation, replacement or modification of the anatomy or of a physiological process
>
> — control of conception,
>
> and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Since Help4Mood has a strong monitoring component, it falls under the definition of medical device. Help4Mood uses specialised hardware (García-González et al., 2012; Mehdavi et al, 2012) to monitor sleep and activity, and specialised software to ask patients about their mood and thoughts and to track further psychomotor symptoms such as speech. This makes it an active medical device for diagnosis:

> Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities. (Annex IX, Section 1.6, MDD 93/42/EC)

Since Help4Mood is restricted to non-invasive monitoring, it is a Class I medical device.

Help4Mood is intended to be used both in private practice and in the health service in three different countries, Spain, Romania, and the UK. The UK requires that medical devices which are deployed in trials should be CE marked.

Very roughly, CE marking is achieved by documenting that the development process of a product has followed a set of procedures that should ensure high quality and minimal risk for the user. Relevant norms are listed in Table 1. Only the generic ISO numbers are given. While there are slightly different variants of these norms for each country, once a product has achieved the CE mark, and adheres to European harmonised standards, the certification is valid for every country of the European Union.

The norms focus on quality management, which goes hand in hand with stringent documentation of the product development cycle and the product itself. Quality management is informed by a thorough risk assessment.

3. THE EFFECT ON HELP4MOOD

3.1 Consequences for Design

The biggest risk in any system that monitors mental health conditions is failure to detect when people are likely to harm themselves or others, or when people are likely to kill themselves.

Predicting suicides or suicide attempts is a highly inexact science (May et al, 2012). At present, there is very little monitoring data from people who have strong suicidal ideation.

Therefore, any part of Help4Mood that would allow users to indicate that they are thinking of suicide would need to be assessed regularly by a human, to ensure no signs are missed.

In Help4Mood, we decided to implement only one check for suicidal ideation, the ninth item of the PHQ-9, which is administered fortnightly. This item asks about the frequency of thoughts of self-harm or suicide. As soon as people report having such thoughts about half the time, health services are automatically alerted.

While users are encouraged to keep regular diaries for their own use, these diaries are not analysed automatically, summarised, or fed back to the professional who cares for the user. Otherwise, all diary entries would have to be checked within a strict time limit by a human to make sure that the user does not show any strong suicidal thoughts.

Although there is a substantial data set of suicide notes that has been processed automatically by different groups

(Chapman et al, 2011), there is at present no similar large database of personal writing that could be analysed to detect markers of suicidal thoughts.

Instead of diary analysis, common negative thoughts will be elicited through a task that is based on an existing instrument used in cognitive behaviour therapy. Users need to indicate an area of their life that they were particularly unhappy with. They are then presented with a set of negative thoughts that might reflect what they felt, and are given guidance on challenging these thoughts.

3.2 Effect on Implementation

Implementing a research prototype following the relevant software development guidelines mentioned in Table 1 is almost impossible, unless the prototype is developed by an organisation that has certifiable and auditable processes in place.

Since none of the consortium partners who are involved in the implementation of Help4Mood has such processes in place, one of the outputs of Help4Mood will be an extensive, formal specification for reimplementing relevant parts of the prototype together with a detailed functional specification of the system and a risk assessment.

Table 1: *Relevant ISO norms that need to be adhered to.*

Norm	***Covers***
ISO 13485	*Quality Assessment*
ISO 14971	*Risk assessment*
ISO 980 *ISO 1041*	*Labelling and Documentation*
ISO 62304 *ISO 62366*	*Software Development and Usability Engineering*

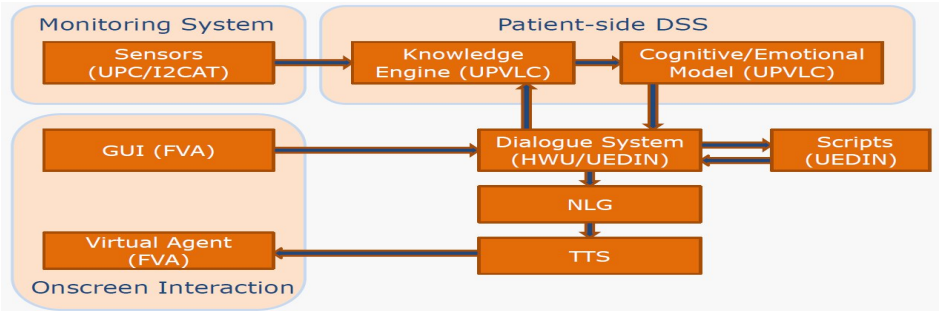

Figure 1: *The Structure of Help4Mood. The system is controlled by the patient-side decision support system (DSS) which receives data both from the physical monitoring system and through on screen interaction with the patient, and processes and summarises this data. The GUI features a virtual agent, who is essentially a talking head. The dialogue system creates the text that is spoken by the virtual agent, first as a string of utterances (Natural Language Generation, NLG), then, as an acoustic message (Text to Speech, TTS)*

4. CONCLUSION

When planning a system to support the treatment of people with depression, it is important to consider the requirements of integration with the health service. If monitoring data is passed on to clinicians, the likelihood is high that the resulting system will fall under Medical Device regulations. Depending on the Ethical Guidelines of the country that the system will be deployed in, this can make it next to impossible to conduct a reasonably large trial within a research project, unless the programming of the relevant prototype is outsourced to an organisation that has relevant quality management certifications and is regularly audited.

The assessment of risks, on the other hand, is a prerequisite for the ethical analysis of research projects in psychiatry and psychotherapy. While some applications, such as automatic detection of negative thoughts or thoughts of self

harm and suicide from patient diaries may appear like a fascinating challenge at first, data collection has substantial ethical challenges.

5. REFERENCES

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