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TOPICAL REVIEW

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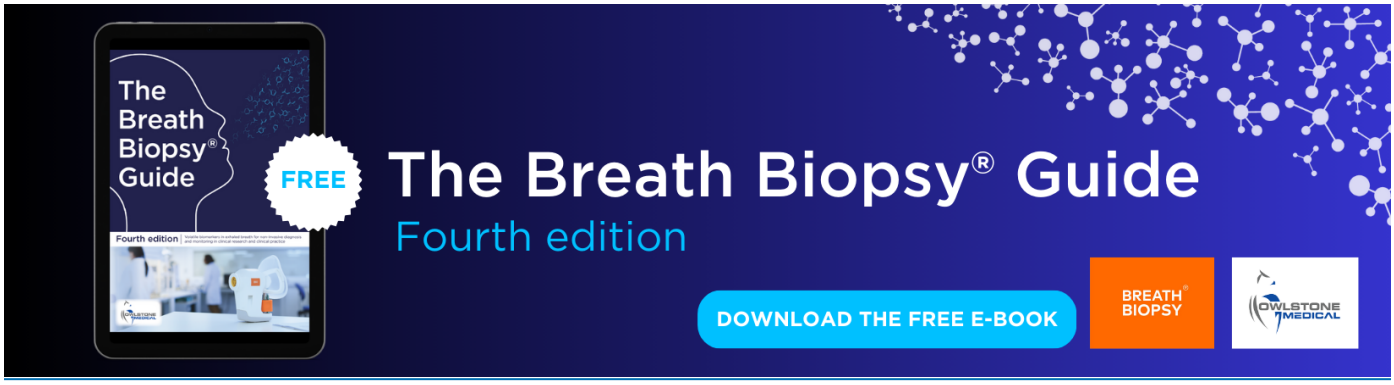
To cite this article: Joachim Behar *et al* 2013 *Physiol. Meas.* **34** R29



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Physiol. Meas. **34** (2013) R29–R46 doi:10.1088/0967-3334/34/7/R29

TOPICAL REVIEW

A review of current sleep screening applications for smartphones

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Received 19 December 2012, accepted for publication 30 May 2013
Published 17 June 2013
Online at stacks.iop.org/PM/34/R29

Abstract

Sleep disorders are a common problem and contribute to a wide range of healthcare issues. The societal and financial costs of sleep disorders are enormous. Sleep-related disorders are often diagnosed with an overnight sleep test called a polysomnogram, or sleep study involving the measurement of brain activity through the electroencephalogram. Other parameters monitored include oxygen saturation, respiratory effort, cardiac activity (through the electrocardiogram), as well as video recording, sound and movement activity. Monitoring can be costly and removes the patients from their normal sleeping environment, preventing repeated unbiased studies. The recent increase in adoption of smartphones, with high quality on-board sensors has led to the proliferation of many sleep screening applications running on the phone. However, with the exception of simple questionnaires, no existing sleep-related application available for smartphones is based on scientific evidence. This paper reviews the existing smartphone applications landscape used in the field of sleep disorders and proposes possible advances to improve screening approaches.

Keywords: actigraphy, audio, mHealth, obstructive sleep apnoea, sleep disorders

(Some figures may appear in colour only in the online journal)

1. Introduction

Sleep disorders are common and contribute to a wide range of healthcare issues including cardiovascular disease and mental health. Sleep disturbances include insomnia, central nervous system hypersomnias, circadian rhythm sleep disturbances, parasomnias, sleep-related movement disorders, and sleep-disordered breathing (Panossian and Avidan 2009).

The societal and financial costs of such disorders are enormous. In Australia alone, the total financial costs (excluding the cost of suffering) amounted to 0.8% of the national gross domestic product in 2006, and represented 1.4% of the total national burden of disease (Hillman *et al* 2006). This picture is reflected around the world (Tan and Marra 2006). For example, problems with falling asleep or daytime sleepiness affect approximately 35 to 40% of the US adult population and are a significant cause of morbidity and mortality (Hossain and Shapiro 2002). However, the prevalence, burden, and management of sleep disorders are often under-estimated or overlooked leading to undertreatment of sleep disorders. A detailed review of sleep disorders can be found in Richert and Baran (2003) and Panossian and Avidan (2009).

One particularly common but under-diagnosed sleeping disorder that affects both children and adults is obstructive sleep apnoea (OSA) (Flemons *et al* 2003). It is characterized by periods of breathing cessation (apnoea) and periods of reduced breathing effort (hypopnoea) during sleep due to the complete or partial collapse of the upper airway. As there is no air flowing into the lungs, the arterial oxygen levels drop and carbon dioxide levels rise. There are also increasingly negative pressure swings in the thorax. Blood pressure initially drops and then drifts upwards during the episode. Eventually the patient awakens with a surge of sympathetic nervous system activity leading to a spike in heart rate and blood pressure and resumption of breathing (Collop 2007). These repeated arousals cause sleep fragmentation which leads to daytime sleepiness (Collop 2007). OSA has been shown to increase the risk of motor vehicle accidents, hypertension, stroke, heart disease and diabetes (Antic *et al* 2009, Collop 2007) and is prevalent around the world. The prevalence of OSA ranges from 2% to 7.5% depending on gender and race or location (Bearpark *et al* 1995, Bixler *et al* 2001, Ip *et al* 2001, 2004, Kim *et al* 2004, Lam *et al* 2007, Sharma *et al* 2006, Udwadia *et al* 2004, Young *et al* 1993).

Diagnosis of sleep-related disorders, and OSA in particular, is usually based on meticulous review of the clinical history of the patient and a physical examination. In some cases referral to a sleep laboratory for further evaluation with polysomnography (a 'sleep study'). An overnight polysomnogram (PSG) is considered the gold standard for the diagnosis of OSA. However, PSGs are expensive, costing between $788 (Deutsch *et al* 2006) and €1057 (Bruyneel *et al* 2011, Masa *et al* 2011), and are limited by the number of beds available in the hospital and the number of sleep specialists in the area. There are many home sleep recording systems on the market which aim to reduce the financial cost and reach a larger population by reducing the number of parameters recorded (Hesselbacher *et al* 2011). Examples include the type II Sleepscan Netlink Traveller (Bio-Logic Systems, Mundelein, Illinois, USA) that can be configured to perform up to 40 channels of data recording; the type II Vitaport-4 PSG (TEMEC Instruments, Kerkrade, Netherlands) with 23 channels; the type IV Visi Grey Flash (Stowood Scientific Instruments, Bleckley, UK) with 6 channels; and the single-channel EEG type IV BioSomnia (OBS Medical, Abingdon, Oxfordshire, UK) (Schweitzer *et al* 2004).

However, if no clinical expert is available, the patient, who has no medical or technical training, must place the sensors in the correct positions. If done incorrectly, the results may be inconclusive, and even if done correctly there may not be a trained specialist readily available to analyse the data. It has been estimated that up to 90% of people with OSA are undiagnosed and untreated (Young *et al* 1997). Flemons *et al* (2004) focused on determining the wait time for diagnosis and treatment with the standard, high cost continuous positive airway pressure, in five different countries which ranged from 2 months in Belgium to 60 months in the UK. The authors postulate that the wait times resulted from the limited beds available for sleep studies in each country, as well as a lack of sleep specialists to score the data. Therefore, a home diagnostic device that is readily available and aids in scoring the data would be beneficial, and ideally would considerably reduce the time to diagnosis and treatment, and overall costs.

Once diagnosed, a range of treatments for OSA are available including changing diet and lifestyle, pharmacological treatments, therapeutic devices (such as oral appliances that physically modify the upper airway whilst being worn (Ferguson *et al* 2006)) surgery, and assistive devices including positive airway pressure devices which are the most commonly used therapy for OSA (Guilleminault and Abad 2004). These are typical treatments available to sufferers of OSA in the developed world. Although the same treatments can also be used in developing countries, cost considerations and supply infrastructure limitations severely restrict their availability. However, if a low cost monitoring device was available, it may be possible to track a patient's response to simple low cost interventions and accelerate or personalize the introduction of new scientifically evaluated therapies.

Smartphones are powerful tools that offer both computational and communication opportunities which can be leveraged for the benefit of healthcare. In the case of OSA screening, two sensors on the phone are of particular interest: actigraphy and audio. One of the most common and easiest way of assessing sleep is through actigraphy measurements. Actigraphy involves wearing a small portable device (called an actigraph) that senses physical motion. Sleep quality testing is based on the principle that movement is reduced during sleep and that consequently sleep-wake patterns can be estimated from periods of activity and inactivity based on movement (Littner *et al* 2003). Audio is an under-used signal that provides information regarding respiratory activity during sleep, and therefore may be a useful tool for determining whether a subject has sleep apnoea (SA) (Pevernagie *et al* 2010). Audio can be recorded using the internal microphone of a mobile phone, which many applications do, or using an external microphone placed either on- or off-body. However, it is important to note the varying quality of sound cards and microphones supplied or available for each phone (see section 2.3).

A number of smartphone applications for sleep disorder screening have been released over the past few years (see section 2). However there is a lack of scientific evidence regarding their clinical efficacy. In this paper we review existing sleep applications available for smartphones with a particular focus on their use for OSA screening.

2. Review of existing home screening apps

Currently, smartphones have matured as a ubiquitous powerful computing platform and acquired improved functionality due to a rich set of embedded sensors, such as accelerometers, gyroscopes, microphones and cameras. Collectively, the data from these sensors can be used for sleep screening and diagnosis and have been used extensively in many available sleep apps (table 1). However, none of these sleep-related apps qualifies as a medical device, according to FDA requirements (USFDA 2013) and there is no scientific evidence validating their clinical effectiveness. In this section we review the three main sources of information used for assessing sleep disturbances using the phone; questionnaire answers, actigraphy and audio signals. In this paper we focus on signals/sources of information that are derived from the phone's built-in sensors by opposition to using additional signals derived from other sensors such as pulse oximetry or electrocardiography that would require to purchase medical equipment.

2.1. Questionnaires

Questionnaires are commonly used as a first screening layer for SA. For example the Epworth Sleepiness Scale (ESS) (Johns 1991), the Berlin Questionnaire (BQ) (Netzer *et al* 1999), or the STOP BANG questionnaire (Chung *et al* 2008). All scales have demonstrated variable results. Several mobile apps are simply just digital implementations of such scales (see table 1).

Table 1. Sleep-related mobile phone apps available on the market (Apple App Store and Android Market). Apps with the single intent of warning and training users to avoid snoring or moving to their back, by mobile phone vibration or buzzing, were excluded from this list since they do not store any information at all during sleep time. ♯ = Snore monitoring, ♭ = Sleep monitoring, ♮ = sleep screening questionnaire, SA = sleep apnoea.

App name	Recorded parameters	Metric score
Snore Sleep Inspector (GRsoft Labs) ♯	Audio (calibration: auto detect room noise levels)	Loudness (power) graph and noise disturbance (ND) counter
Snore Spectrum/Snore Keeper (ZURLIN Technologies) ♯	Audio	Time-series graphs, loudness (power) distribution graph, records the top five ND according to an adjustable noise threshold, Snore Spectrum Index (average frequency content of captured sound) and Total Snore Index (average snores per hour)
Owl (Rorobo Team) ♯	Audio	Snoring (time-series) graph and undefined statistics
Do I snore? Geode Software Ltd) ♯	Audio	Records the top three ND according to an undefined statistic
SnoreRecorderPro (MusicalSoundLab) ♯	Audio	ND counter (adjustable noise threshold)
Anti Snore—The snore killer (Signs Studios) ♯	Audio	ND counter (adjustable noise threshold)
Sleep Analyser (Excelltech Inc.) ♯	Audio	ND counter (adjustable noise threshold)
Snore No More (AuxylCorp) ♯	Audio	ND counter (adjustable noise threshold) and time-series graphs
Snoring U (Pointer Software Systems) ♯	Audio	Time-series graphs and relative ND time
Babbler Pro Audio Recorde (IT Adapter Corp. Inc.) ♯	Audio	Time-series graphs and ND counter
Sleep Sounds Recorder (Arawella Corporation) ♯	Audio	Time-series graphs (sounds recorded only if detected)
ResMed Sleep Assessment (ResMed) ♯ ♮	Audio	STOP BANG questionnaire (Chung *et al* 2008), time-series graphs (compare recordings with examples of typical snoring and SA events)
Sleep Appnea: A Sleep Analyser (Ashwin Madavan) ♯ ♭	Audio	ND (SA events) counter (per hour), AHI index and severity of SA
Wakemate (REM Solutions) ♭	Actigraphy (external wristband)	Actigram and undefined statistics
Zeo Sleep Manager (Zeo) ♭	Actigraphy (external headband)	Actigram and undefined statistics
ElectricSleep (Zeo) ♭	Actigraphy (with calibration)	Actigram and undefined statistics
Sleep Checker (Apps&U) ♭	Actigraphy	Actigram and undefined statistics
Smart Alarm Clock (Alexander Kosenkov) ♭	Actigraphy	Actigram
Sleep Cycle Alarm Clock (Maciek Drejak Labs AB) ♭	Actigraphy	Actigram
Sleep Time - Alarm Clock (Azumio Inc.) ♭	Actigraphy	Actigram
Relax Timer - Sleep Cycle (Master B) ♭	Actigraphy	Actigram

Table 1. (Continued.)

App name	Recorded parameters	Metric score
GN&GM: Smart Alarm Clock! (Flysoft) ♭	Actigraphy	Actigram
Smart Alarm Lite (Kyoto Applications) ♭	Actigraphy	Actigram
Sleep Science Alarm (Brett Galbraith) ♭	Actigraphy	Actigram
Absalt EasyWakeup PRO (Absalt) ♭	Actigraphy	Actigram
SmoothAlarm PRO (JotWee) ♯ ♭	Actigraphy (with calibration) and audio	Actigram, ND counter and Sleep Quality Index (SQI: ratio between amount of deep sleep and the total sleep)
WakeApp (AppZoo GmbH) ♯ ♭	Actigraphy and audio	Time-series graphs, actigram, ND counter and SQI
SnoreMonitor SleepLab (Adactive AB) ♯ ♭	Actigraphy (chest movement) and audio (with calibration)	ND counter (adjustable noise threshold), time-series graphs, actigram and sleeping positions
Smart Alarm Clock (Viaden Mobile) ♯ ♭	Actigraphy and audio	Time-series graphs, actigrams and ND counter
Anti Snore—sleep laboratory (i-Forge Mobile) ♯ ♭	Actigraphy and audio	Time-series graphs, actigram and sleeping positions
Sleep as an Droid (Petr Nalevka) ♯ ♭	Actigraphy and audio	Time-series graphs, actigram and undefined statistics
Are U Sleepy? Sleep apnoea Risk (Stefano Picciolo) ♮	Questionnaire only	Berlin questionnaire (Netzer *et al* 1999); Epworth Sleepiness Scale (Johns 1991); Flemons formula (Flemons and Reimer 1998); STOP BANG questionnaire Chung *et al* 2008)
Obstructive Sleep apnoea Screener (Diastolic ♮ Robotics Inc.)	Questionnaire only	American Society of Anesthesiologists checklist (Gross *et al* 2006); Berlin questionnaire (Netzer *et al* 1999); STOP and STOP BANG questionnaire (Chung *et al* 2008)
Home Sleep apnoea A-Z (My Mobile Fans) ♮	Questionnaire only	Berlin questionnaire (Netzer *et al* 1999) and Epworth Sleepiness Scale (Johns 1991)
Sleep&Cardio (Philips Healthcare) ♮	Questionnaire only	Unreferenced sleep quiz
SnoreClock (Ralph's Mobile Apps) ♯	Audio	Time-series graphs and ND counter
Home Sleep Apnea A-Z (Aviisha Medical Institute)	Questionnaire only	Berlin questionnaire (Netzer *et al* 1999); Epworth Sleepiness Scale (Johns 1991)
Snore Check (SnoreCheck) ♯	Audio and questionnaire	STOP BANG questionnaire variant
SnoreLab (Reviva Softworks Ltd) ♯	Audio	Time-series graphs and undefined statistics
Sleep Talk Recorder (MadInSweden AB) ♭	Audio	Time-series graphs
SleepTester (Total Sleep Management Inc) ♮	Questionnaire only	Epworth Sleepiness Scale (Johns 1991)

The ESS (Johns 1991) is a clinical tool used for assessing daytime sleepiness. The maximum ESS score is 24. ESS < 11, ESS $\in [11; 14]$, ESS $\in [15; 18]$ and ESS > 18 are classified as normal, mild subjective daytime sleepiness, moderate subjective daytime sleepiness and severe subjective daytime sleepiness respectively (Parkes *et al* 1998). The correlation between ESS and OSA severity has demonstrated to be relatively weak (Scottish

Intercollegiate Guidelines Network 2003). The BQ was designed to identify patients at risk for the SA syndrome. Ahmadi *et al* (2008) assessed the BQ on 130 sleep clinic patients and reported 62% sensitivity (Se) and 43% specificity (Sp) at the respiratory disturbance index (RDI[1]) > 10. The authors concluded that the BQ was not an appropriate instrument for identifying patients with SA in a sleep clinic population (Ahmadi *et al* 2008). The Calgary SA Quality of Life Index (CSAQLI), also called the Flemons' questionnaire (Flemons and Reimer 1998), is a non-clinical questionnaire that evaluates health-related quality of life in patients with SA. Chung *et al* (2008) developed the STOP BANG questionnaire for OSA screening in surgical patients (i.e. patients about to undergo a surgical operation). This questionnaire requires information on snoring, tiredness during daytime, existence of observed apnoea, high blood pressure, body mass index, age, neck circumference and gender. The STOP BANG questionnaire was completed by 2974 patients in the preoperative clinics of Toronto Western Hospital and Mount Sinai Hospital, Toronto, Ontario, Canada. Of all patients who were invited, 211 patients agreed and came to undergo polysomnography, 34 for the pilot study test and 177 for validation. Respective sensitivities of 83.6%, 92.9% and 100% with corresponding specificity of 56.4%, 43% and 37% were found for Apnoea–hypopnoea index (AHI[2]) greater than 5, 15, and 30. Such performance is of questionable use but the components of the questionnaire may provide useful additional information when combined with direct physiological monitoring.

Following the review of the existing questionnaires for OSA screening we therefore concluded that a STOP BANG-based questionnaire should be used for OSA screening.

2.2. Actigraphy recording and body position

Sleep-related mobile apps (table 1) mainly infer wakefulness and sleep from the presence or absence of limb movement extracted from the mobile phone's inbuilt accelerometer. In order for a patient to adjust their sleeping position and eventually sleeping habits, body position can also be extracted from the accelerometer. As demonstrated in table 1, two apps (SnoreMonitor Pro and Anti Snore—sleep laboratory) display body position, where the latter emits a sound of a *fading mosquito* to provoke an adjustment of the patient sleeping position if snoring is detected.

Recently, Natale *et al* (2012) compared actigraphy based sleep statistics derived from the Actiwatch (Cambridge Neurotechnology Ltd, Cambridge, UK) and an iPhone (Apple Inc, Cupertino California, USA) smartphone. Actigraphy time series from 13 young healthy volunteers were recorded by the two devices and compared at equivalent epochs (once every minute). The Actiwatch was worn on the dominant wrist and the iPhone was placed under the pillow. Standard sleep statistics (Total Sleep Time, Wake After Sleep Onset, Sleep Efficiency and Sleep Onset Latency) were estimated and were found to have significant differences especially Sleep Onset Latency. Moreover, actigraphy is known to be a poor proxy for sleep quality in unhealthy patients (Sadeh 2011), it appears likely that placing a smartphone in the bed of the subject is not an acceptable screening solution using standard sleep metrics. This does not preclude the use of a smartphone for accurate sleep quality assessment and diagnosis, but new data processing algorithms will be needed.

Actigraphy, used for sleep-wake assessment, was found to be very good at detecting sleep episodes (Se in the high 90s) but not wake episodes (Sp in the range 30–50%) when looking at healthy populations (Sitnick *et al* 2008, Insana *et al* 2010, Paquet *et al* 2007, De Souza *et al* 2003). However, actigraphy is not good at resolving sleep structure (Sadeh 2011). Regarding

[1] The RDI definition in the context of the study by Ahmadi *et al* (2008) is defined as the total number of apnoeic and hypopneic episodes per hour of sleep. As such it is equivalent to the AHI here.

[2] The AHI corresponds to the number of apnoea and hypopnoea events per hour of sleep and is typically used to assess the severity of SA.

special populations (e.g. elderly people or individuals with poor sleep quality) the validity of actigraphy is more questionable. Therefore, it was recommended that actigraphy be combined with other sensor modalities (Sadeh 2011). Actigraphy has been shown to overestimate sleep time in subjects with insomnia due to individuals lying motionless for extended periods (Se = 95.2% and Sp = 36.3%) (Sivertsen *et al* 2006, Natale *et al* 2009) when actimeters are worn in different positions, while Middelkoop *et al* (1995) found that actigraphy was insufficient by itself to identify reliably individuals who suffer from OSA (for an apnoea index $\geqslant$5, Se = 5% and Sp = 100%).

It has been shown that there is a correlation between the severity of sleep apnoeic events and body position (Oksenberg *et al* 2000). Publications relating to the effect of body posture on OSA have shown that the severity of OSA increases when sleeping in the supine posture (Lloyd and Cartwright 1987, Kavey *et al* 1985, Cartwright 1984). For this reason patient position (typically left, right, prone, supine, sitting up) are often recorded overnight and used as an adjunct to other signals for diagnosis and advising patients in changes to their sleeping habits. Body position can thus be recorded on the phone, along with actigraphy as another measure of body activity during sleep.

However, it should be noted that none of the current apps available on the market provide useful details about their actigraphy analysis algorithms, and identify the scientific publications on which they may be based. We therefore must conclude that the outputs of all actigraphic-based sleep analysis apps should not be used for anything more than a qualitative feeling of how a user's sleep may differ from night to night. Moreover, actigraphy recorded by a phone is entirely different from that recorded in standard sleep monitoring. In general, the latter use actigraphs attached to the extremities. A complete recalibration and re-evaluation of the algorithms would be needed for use on a mobile phone.

2.3. Audio recording

Of the sleep apps currently available, many record audio (see table 1). However, as with those based on actigraphy, none of them use audio to classify a user as having OSA or not; the audio is processed to provide metrics or graphs which give the user a qualitative impression of how well they may have slept. Therefore, they provide no clear scientifically tested rating which can provide any actionable information.

Some of the apps provide samples of what normal breathing, snoring and apnoeic episode actually sound like so that the user might replay their own recordings and try to recognize the problem for themselves. However, without significant training and testing of the user, significant mistakes are likely to be made. Some of the apps display the audio time series, allowing the user to scroll through their night's sleep and manually (and subjectively) identify periods of sleep that seem disturbed or abnormal to the user. Other apps provide a 'noise disturbance' counter which tells the user the number of times the audio was above either a fixed or an adjustable threshold. A number of the apps quote statistics which are not defined. The snore *spectrum/snore keeper* app provides the 'power distribution graph', the 'snore spectrum index' (which the app defines as the average frequency content of captured sound) and 'total snore index' (defined as average snores per hour). Importantly however, no useful descriptions are given on how such non-standard quantities are calculated and they therefore cannot be interpreted. Audio can be used to classify subjects, either by finding individual events or by analysing the entire time series (Pevernagie *et al* 2010, Roebuck and Clifford 2012), instead of being used only as an indicator of sleep quality, or an educational tool. However, no currently publicly available apps provide this facility.

Table 2. Frequency of different relevant respiratory events.

Event	Inspiration	Expiration
Wheezes (Chowdhury and Majumder 1982)	800 Hz	1200 Hz
Crackles (Chowdhury and Majumder 1982)	400 Hz	2000 Hz
Rubs (Chowdhury and Majumder 1982)	800 Hz	1200 Hz
Stimulated nasal snoring (Liistro *et al* 1991)	104.2 ± 18.9 Hz	70.0 ± 21.6 Hz
Stimulated mouth snoring (Liistro *et al* 1991)	31.5 ± 7.3 Hz	96.7 ± 13.4 Hz

The audio file recorded by the mobile phone has to be of sufficient quality in order to preserve all the features of the signal with their potential associated diagnostic information. According to Pevernagie *et al* (2010) snoring occurs mainly on inspiration. Liistro *et al* (1991) did find some frequency components on expiration, however the results were on stimulated nasal and mouth snoring. Hill *et al* (1999) noted that the majority of snores contain a broad spectrum of frequencies, but palatal vibration produces marked peaks and troughs, or impulses of sound loudness at low frequencies, usually below 50 Hz. Although, other studies have shown that the frequency band of interest for snoring is 20Hz–5.5 kHz (Dalmasso and Prota 1996, Fiz *et al* 1996). Table 2 summarizes the characteristic frequencies or frequency bands of different relevant respiratory events. There are multiple parameters in the audio acquisition workflow that have an impact on the audio quality: frequency response of the phone's audio card, audio media format (encoder and associated compression algorithm), type/quality of microphone in the hands-free head set, and the location of the microphone in relation to the subject (e.g. on body or off body). In contrast to the standard clinical setting, there also may be issues such as external noise (from sirens, dogs barking, audio-visual equipment, neighbours, co-sleeping and artefacts due to reflections off large structures in the room which might confuse some energy- and frequency-based detectors.

The sound card (audio analogue-to-digital converter) of the phone must have a relatively flat frequency response in the frequency band of interest (20 Hz–5.5 kHz) so that little distortion appears in the recording. However the variable amplitude and phase response of each sound card and microphone supplied with each phone model means that any app's response is likely to be highly influenced by distortion that may result. Moreover, any significant differences in the audio profile of the phone's sound card and the sound card used to capture the data on which the app was trained or calibrated, could confuse any classifier. GSMArena (2011) provides an excellent resource for comparing audio response and quality/distortion levels for a wide range of smartphones and is continually updated. An example is shown in figure 1 where the frequency response of the HTC Wildfire is compared to the Sony-Ericsson Experia Mini Pro. Note that the latter provides a much better low-end frequency response and is likely to provide less distortion of the clinically useful audio information such as snoring, choking and coughing.

2.4. Other physiological signals

Although blood oxygen saturation level is excellent at identifying oxygen desaturations associated with apnoeic events (Fietze *et al* 2004), it is not obvious that the oxygen desaturation index should be calculated in a self-monitoring scenario (with a smartphone app). This is due to the fact there is currently no reliable way of monitoring oxygen saturation during sleep using only a mobile phone. Instead using a mobile phone and a pulse oximeter that connects directly or via Bluetooth to the phone is required. This is currently unrealistic for a low cost systems, until the commercial price of oximeters with such functionality is addressed. Utilizing a pulse oximeter in a phone based sleep monitoring system increases the cost and reduces the

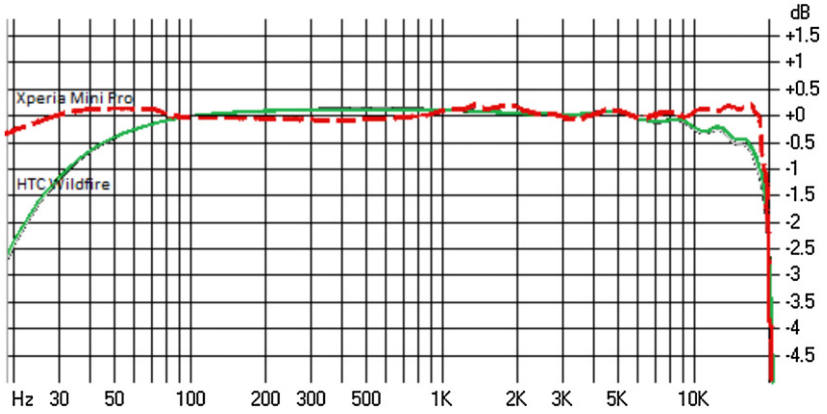

Figure 1. HTC sound card frequency response of the HTC Wildfire (solid green line) and Sony Ericsson Xperia Mini Pro (dashed red line). Adapted from GSMArena (2011).

accessibility for the users particularly in developing countries. Moreover, if a pulse oximeter is not connected accurately, the resulting noisy signal can actually degrade the performance of the screening system. Even in a highly controlled monitoring scenario (such as the intensive care unit) an oximeter can produce noisy readings up to 20% of the time (Li and Clifford 2012). A sleep-related screening tool should be focused on users with relatively little to no training in physiological monitoring and not require the purchase of additional medical equipment. The same logic is true for other physiological sensors such as the electrocardiogram.

2.5. Video analysis

Video is commonly used to verify diagnoses and therefore could provide additional information characterizing movement and behaviour to help diagnosing OSA. With the prevalence of video capture capabilities on smartphones, video could be recorded over night by positioning the phone off body with the video camera pointing at the subject. Although no apps currently have such a facility, it has been suggested by Gederi and Clifford (2012). However, such approaches would have to deal with the issue of monitoring a patient in the dark. This may be possible if the infrared filter is removed from the front of the camera lens (but that is a non-trivial hack, which may lead to damage of the lens) and with an infrared ambient light in the room. In some cases the filter is painted onto the lens and chemicals may be required to remove it.

2.6. Operating system

There are a number of suitable mobile phone Operating Systems (OS) available, with the main ones being: Android, RIM, iOS, Windows 7 mobile and Windows Phone 8. The main two discriminatory factors for choosing the OS are: (1) how widespread is it? and (2) how homogeneous is the hardware of the phones using this OS? Indeed, a widespread OS is synonymous with higher user rate. Hardware homogeneity is important with respect to the portability of the signal processing methods which parameters are usually tuned on signal recorded by a limited number of hardware types. However, Android OS with its recent exponential growth, particularly in developing countries, (Canalys 2011) is probably the best choice according to the first criteria but the iPhone with its rather homogeneous hardware better satisfy the second criteria.

2.7. Summary

In summary, most of the apps make use of the phone accelerometer, sound recorder and answers to various questionnaires to provide feedback to the users on how well they are sleeping. With the exception of some of the sleep scales, none of the apps provide any scientifically validated feedback. Moreover, none of these apps uses the combination of the different signals along with patient information provided by the questionnaire. In the next section, we motivate a framework for mobile sleep application which fuses prior information (from a brief standardized questionnaire), audio information (for snore cues), body movement and position data to provide a probability that the subject suffers from OSA.

3. Approaching evidence-based development of a sleep app

In this section we outline the major critical engineering issues which need to be addressed in order to create a scientifically validated (and hence useful) sleep monitoring and screening app.

3.1. False alarm reduction and pre-screening

One major issue of providing the general public with the power to self-diagnose through a mobile phone is that mass use is likely to lead to enormous numbers of false alarms. In turn, this may lead to large-scale inappropriate resource allocation or may even overwhelm the healthcare system, even if the app is 99% accurate. It is therefore important to only screen for a disease after passing a differential diagnostic test similar to that which a general practitioner might apply. Fortunately, the addition of such a decision support mechanism on the phone is often possible through a simple menu system. For example, the STOP-BANG questionnaire could act as a pre-screening mechanism, which would provide risk stratification prior. Without achieving a 'high' risk of OSA, it would be unwise to continue to perform any diagnostic recording. Alternatively, if the app was retrained on a larger population which included the 'worried well' then the factors involved in the STOP-BANG questionnaire could be added to any predictive model which provided a diagnostic assessment.

3.2. Signal structure and feature extraction

There are many algorithms and processes that could be used to analyse the data collected on the phone. The algorithms should have shown good performance, particularly on data collected in a home setting as that is where the app is going to be used. Ideally, the algorithm should not be too complex in order to run on the phone; although this may not be necessary as data can be transferred to the cloud and processed there. In either case, speed of processing is important as it is likely that the user be unwilling to wait for hours for a prediction. A detailed description of the signals recorded during sleep and how they are analysed can be found in Roebuck *et al* (2013), some of which could be used on a phone.

In terms of audio, most of the techniques mentioned in Roebuck *et al* (2013) would require an event detector. Each event would need to be identified before features could be extracted from them, such as looking at formant frequencies (Ng *et al* 2008), cepstral coefficients (Duckitt *et al* 2006) or frequency components (Fiz *et al* 1996, Cavusoglu *et al* 2007). Instead, the minimum amount of pre-processing would be ideal. The method of multiscale entropy (MSE) as used by Roebuck and Clifford (2012) is a good alternative as there is no event identification required, the data is minimally processed which can be done on the phone, and the algorithm for calculating MSE can be run on the phone in real time. It has provided good

results on data collected in the home with a sensitivity of 90.5% and a positive predictive value of 83.5% on out-of-sample test data (using 146 subjects)).

Total sleep time derived from actigraphy has been shown to assist the calculation of AHI in simplified sleep screening scenarios (where total time in bed would otherwise be used) (Elbaz *et al* 2002). Furthermore, actigraphy based sleep-wake assessment can be used to identify movement (wake or REM) periods against non-movement (sleep or REM) periods. A variety of methods have been studied to identify these periods (Cole *et al* 1992, Sadeh *et al* 1994) but it has been shown that actigraphy used in this way is not good at identifying sleep-disordered breathing, such as OSA (Sadeh and Acebo 2002, Sadeh 2011). Higgins (2012) applied MSE to actigraphy data, and, along with neck size, achieved an accuracy of 74.5%, a sensitivity of 68.2% and a specificity of 79.6% on the test set (337 subjects). Similar to this approach, MSE applied to activity derived from video recordings of sleep (with minimum preprocessing of videos) has been used (Gederi and Clifford 2012) to identify patterns of sleep-disordered breathing, such as OSA with an accuracy of 90%, a sensitivity of 80% and a specificity of 100%. Generally speaking, camera recordings provide an alternative method to accelerometry to achieve non-contact monitoring of sleep activity.

Finally fusing the features extracted by these algorithms and the individual answers from the pre-screening questionnaire is likely to provide a better classification than using any of them individually.

4. Regulatory issues

The existence of regulatory barriers in the context of mobile apps is a complex and rapidly evolving matter. While stand-alone software can be deemed a medical device under the EU Council Medical Device Directive (MDD) 93/42/EEC (European Union 2013), the definitions are not explicit and thus are open to interpretation. Regarding CE marking, the MDD 93/42/EEC is the primary source of regulation governing health apps across European member states. In essence, manufacturers must firstly determine whether their device is a medical device, and if so, what is the most appropriate classification according to the directive. The MDD then defines how medical devices should be regulated according to their classifications, and what marks should be used to demonstrate conformity. Within the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) (Medicines and Products Regulatory Agency 2013) is the competent regulatory agency, running under the MDD, to which all medical devices must be registered. The first medical app approved in the UK, Mersey Burns (Medicapps Ltd, UK), was registered as a medical device by the MHRA and was publicly available for download in 2012. Mersey Burns is a free clinical tool for calculating burn area percentages, prescribing fluids using Parkland formula, background fluids and recording patients' details. It is designed for physicians and runs on the iPad, iPhone, Android and HTML5 compatible browsers.

In the USA, the FDA has recently developed new guidelines (USFDA 2011) covering the definition and regulation of the so called 'mobile medical apps'. Within these guidelines, FDA planned to regulate only a subset of apps that not only meet the definition of a medical device but also are used as an accessory to a regulated medical device or transform a mobile platform into a regulated medical device. The FDA recognizes the extensive variety of actual and potential functions of mobile apps, their potential benefits and risks to public health, and thus has granted pre-market clearance to several manufacturers of mobile medical apps. As a tool intended to assist in the identification of applicable regulations, tables 3 and 4 provide examples of currently regulated devices and their respective class. Class I devices (general controls) is the least demanding of the three FDA device classes. In particular these devices

Table 3. Examples of currently FDA regulated devices, the class according to which they are regulated, and their FDA regulation numbers. This list is not a complete list of products and is intended only to provide clarity and assistance in identification of applicable regulations. Adapted from the USFDA (2013).

FDA regulation number	Examples of currently FDA regulated medical devices	Device class	Submission type ID
876.1500(b)(2)	Accessories, Photographic, For Endoscope (Exclude Light Sources)	I	510(k) exempt
870.2770	Analyser, Body Composition	II	510(k)
868.1890	Calculator, Drug Dose	II	510(k)
868.1890	Calculator, Predicted Values, Pulmonary Function	II	510(k)
868.1880	Calculator, Pulmonary Function Data	II	510(k)
868.1900	Calculator, Pulmonary Function Interpretation (Diagnostic)	II	510(k)
862.2100	Calculator/Data Processing Module, For Clinical Use	I	510(k) exempt
874.3310	Calibrator, Hearing Aid/Earphone And Analysis Systems	II	510(k)
878.4160	Camera, Cine, Microsurgical, With Audio	I	510(k) exempt
878.4160	Camera, Still, Microsurgical	I	510(k) exempt
878.4160	Camera, Television, Endoscopic, With Audio	I	510(k) exempt
870.1110	Computer, Blood-Pressure	II	510(k)
870.1425	Computer, Diagnostic, Programmable	II	510(k)
892.2020	Device, Communications, Images, Ophthalmic	I	510(k) exempt
892.2010	Device, Digital Image Storage, Radiological	I	510(k) exempt
892.2010	Device, Storage, Images, Ophthalmic	I	510(k) exempt
876.1500	Device, Telemedicine, Robotic	II	510(k)
862.2100	Digital Image, Storage And Communications, Non-Diagnostic, Laboratory Information System	I	510(k) exempt
892.2030	Digitizer, Image, Radiological	II	510(k)
892.2030	Digitizer, Images, Ophthalmic	II	510(k)
870.2800	Electrocardiograph, Ambulatory, With Analysis Algorithm	II	510(k)
882.1400	Electroencephalograph—Automatic Event Detection Software For Full-Montage Electroencephalograph	II	510(k)
882.1400	Electroencephalograph—Burst Suppression Detection Software For Electroencephalograph	II	510(k)
882.1400	Electroencephalograph—Index-Generating Electroencephalograph Software	II	510(k)
882.1400	Electroencephalograph—Non-Normalizing Quantitative Electroencephalograph Software	II	510(k)
882.1400	Electroencephalograph—Normalizing Quantitative Electroencephalograph Software	II	510(k)
882.1400	Electroencephalograph—Source Localization Software For Electroencephalograph Or Magnetoencephalograph	II	510(k)
876.1500	Endoscopic Video Imaging System/Component, Gastroenterology-Urology	II	510(k)
884.2225	Imager, Ultrasonic Obstetric-Gynecologic	II	510(k)
876.1500	Led Light Source	II	510(k)
878.4810	Light Based Over The Counter Wrinkle Reduction	II	510(k)
878.4810	Light Based Over-The-Counter Hair Removal	II	510(k)
880.6350	Light, Examination, Medical, Battery Powered	I	510(k) exempt
880.5580	Locator, Acupuncture Point	II	510(k)

Table 3. (Continued.)

FDA regulation number	Examples of currently FDA regulated medical devices	Device class	Submission type ID
870.1875(b)	Lung Sound Monitor	II	510(k)
886.5540	Magnifier, Hand-Held, Low-Vision	I	510(k) exempt
880.6315	Medication Management System, Remote	II	510(k)
884.6190	Microscope And Microscope Accessories, Reproduction, Assisted	I	510(k) exempt
868.2377	Monitor, Apnea, Home Use	II	510(k)
880.2400	Monitor, Bed Patient	I	510(k) exempt
884.2660	Monitor, Blood-Flow, Ultrasonic	II	510(k)
868.2375	Monitor, Breathing Frequency	II	510(k)
870.2300	Monitor, Cardiac (Incl. Cardiotachometer & Rate Alarm)	II	510(k)
886.1510	Monitor, Eye Movement, Diagnostic	II	510(k)
884.2660	Monitor, Fetal Doppler Ultrasound	II	510(k)
884.2730	Monitor, Heart Rate, Fetal, Non-Stress Test (Home Use)	II	510(k)
884.2660	Monitor, Heart Rate, Fetal, Ultrasonic	II	510(k)
884.2660	Monitor, Hemic Sound, Ultrasonic	II	510(k)
884.2640	Monitor, Phonocardiographic, Fetal	II	510(k)
870.2300	Monitor, Physiological, Patient(Without Arrhythmia Detection Or Alarms)	II	510(k)
870.2340	Monitor, St Segment	II	510(k)
884.2660	Monitor, Ultrasonic, Fetal	II	510(k)

are not designed for use in supporting or sustaining life or to be of considerable importance in preventing impairment to human life and may not present a potential unreasonable risk of illness or injury (USFDA 2012). In addition to conformity with general controls, class II or 'medium risk' medical devices must comply with special controls that might include: special labelling requirements, mandatory performance standards, postmarket surveillance and FDA medical device specific guidance (USFDA 2012). Class II devices typically require pre-market notification (only a few are exempt from this) by submission and FDA review of a 510(k) clearance to market submission.

The first medical app cleared by the FDA was Mobile MIM (MIM Software Inc., Cleveland, USA) in 2011 which is a radiology application allowing physicians to view medical images on the iPhone and iPad and make medical diagnoses based on images from computed tomography, magnetic resonance imaging, and nuclear medicine technology, such as positron emission tomography. It is indicated for use only when there is no access to a workstation. This is a significant indication because it implies that data review or analysis may be inferior using a mobile device, but that it is nevertheless acceptable in circumstances of urgency or large cost/inconvenience.

When it comes to classification of stand-alone medical device software products into class I and II, the FDA has, for example, placed laboratory information systems into class I, and picture archiving and communications systems into class II. In 2011, with the release of the new guidelines, the FDA classified Medical Device Data System (MDDS) software as class I, 510(k) exempt devices. This rule defined MDDS software as a restricted category of products that transfer, store, convert, or display medical device data without providing analysis, alarms, or active patient monitoring. Some software programs, including some mobile apps, have also been regulated as 'accessories' to traditional medical devices like glucose meters. Under the 'accessory rule', these devices are typically classified and regulated in the same manner as the parent device. Under the FDA regulation, the sleep app is a medical device of class I if it is considered as an MDDS software. The latest MDD guidance rules written by the

Table 4. Continuation of table 3. Adapted from the USFDA (2013).

FDA regulation number	Examples of currently FDA regulated medical devices	Device class	Submission type ID
884.2720	Monitor, Uterine Contraction, External (For Use In Clinic)	II	510(k)
878.4810	Over-The-Counter Powered Light Based Laser For Acne	II	510(k)
868.2550	Pneumotachometer	II	510(k)
878.4810	Powered Light Based Non-Laser Surgical Instrument	II	510(k)
870.2800	Recorder, Event, Implantable Cardiac, (Without Arrhythmia Detection)	II	510(k)
876.1725	Recorder, External, Pressure, Amplifier & Transducer	II	510(k)
890.5050	Reminder, Medication	I	510(k) exempt
880.2700	Scale, Stand-On, Patient	I	510(k) exempt
864.9175	Software, Blood Bank, stand-alone products	II	510(k)
886.5540	Spectacle Microscope, Low-Vision	I	510(k) exempt
868.1850	Spirometer, Monitoring (W/Wo Alarm)	II	510(k)
870.1875(b)	Stethoscope, Electronic	II	510(k)
868.1920	Stethoscope, Esophageal, With Electrical Conductors	II	510(k)
884.2900	Stethoscope, Fetal	I	510(k) exempt
876.4300	System, Alarm, Electrosurgical	II	510(k)
884.2990	System, Documentation, Breast Lesion	II	510(k)
892.2050	System, Image Processing, Radiological	II	510(k)
892.1560	System, Imaging, Optical Coherence Tomography (Oct)	II	510(k)
884.2800	System, Monitoring, For Progress Of Labour	II	510(k)
884.2740	System, Monitoring, Perinatal	II	510(k)
870.2300	System, Network And Communication, Physiological Monitors	II	510(k)
876.1500	System, Surgical, Computer Controlled Instrument	II	510(k)
864.9175	System, Test, Automated Blood Grouping And Antibody	II	510(k)
880.2910	Thermometer, Electronic, Clinical	II	510(k)
886.1930	Tonometer, Ac-Powered	II	510(k)
870.2920	Transmitters And Receivers, Electrocardiograph, Telephone	II	510(k)
870.2910	Transmitters And Receivers, Physiological Signal, Radiofrequency	II	510(k)
884.2990	System, Documentation, Breast Lesion	II	510(k)
892.2050	System, Image Processing, Radiological	II	510(k)
892.1560	System, Imaging, Optical Coherence Tomography (Oct)	II	510(k)
884.2800	System, Monitoring, For Progress Of Labour	II	510(k)
884.2740	System, Monitoring, Perinatal	II	510(k)
870.2300	System, Network And Communication, Physiological Monitors	II	510(k)
876.1500	System, Surgical, Computer Controlled Instrument	II	510(k)
864.9175	System, Test, Automated Blood Grouping And Antibody	II	510(k)
880.2910	Thermometer, Electronic, Clinical	II	510(k)
886.1930	Tonometer, Ac-Powered	II	510(k)
870.2920	Transmitters And Receivers, Electrocardiograph, Telephone	II	510(k)
870.2910	Transmitters And Receivers, Physiological Signal, Radiofrequency	II	510(k)

European Commission on the classification of medical devices suggests that most apps would be classified under class I. According to the guidance rules of MEDDEV2.4/111 European Commission, DG Health and Consumer (2010), if rule 9, 10 and 11 apply, then a given app may be classified as class IIa or IIb. However, if none of these three rules apply, the app is considered, by default, to be class I under rule 12. The corresponding rules are that the device is not: an active therapeutic device intended to administer or exchange energy (rule 9), an active device for direct diagnosis or monitoring of vital physiological processes (rule 10), an

active device to administer or remove medicines and other substances from the body (rule 11). Under these rules the classification of a sleep app is not straightforward. If the app was only recording signals to be transferred/analysed by a remote physician or other medical devices then it would fall under class I according to the MDD guidance. However, as the introduced app framework is processing the signal on the phone to screen for OSA it is then used as an active device for direct monitoring of vital physiological processes (rule 10) and should fall under class II which requires FDA clearance to market submission.

5. Conclusion

A high percentage of people suffering from OSA and other sleep-related disorders are undiagnosed and, by consequence, untreated, despite OSA having severe health consequences for people with the condition. This produces large follow-on costs for a health care system. The recent increase in adoption of smartphones, with high quality on-board sensors has led to the proliferation of many sleep screening applications running on smartphones. However, our review of the existing app landscape revealed that no existing available app is based on strong scientific evidence, with the exception of those that implement a simple validated questionnaire. Moreover the apps are likely to give highly variable results based on the phone type, the type of patient, where the phone is located relative to the user, and the varying environment in which they are used.

We have therefore motivated an evidence based development of a sleep app using on-board phone sensors and which could be a first step towards clinically-validated automated sleep screening available on a mass scale and at negligible cost to smartphone users.

Acknowledgments

The authors would like to acknowledge the support of the funding agencies: JB acknowledges the support of the Engineering and Physical Sciences Research Council and the Balliol French Anderson scholarship fund; AR, JSD, and EG acknowledge the support of the RCUK Digital Economy Programme grant number EP/G036861/1 (Oxford Centre for Doctoral Training in Healthcare Innovation). The authors would also like to thank professor John Stradling, Professor of Respiratory Medicine for expert advice, and Dr Lyn Davies, Stowood Scientic Instruments Ltd, Beckley, Oxford for technical cooperation and loan of Visi-Download analysis software.

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