

WIRELESS PERSONAL MONITORING OF PATIENT MOVEMENT AND VITAL SIGNS

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ABSTRACT

We describe a clinical trial of wireless personal monitoring devices to detect patient movement and vital signs with the intent to prevent falls. The trial involves wireless data transmission from the devices in a public hospital environment. The paper describes the objectives of the trial and the diligence required to obtain wireless approval for use in clinical areas.

Keywords: personal monitoring, wireless, falls prevention.

APPLICATION

A clinical trial is underway within the Division of Geriatric and Rehabilitation Medicine in a public hospital in Brisbane, Australia. The trial is evaluating several devices that can monitor patient movement and vital signs, with the aim to prevent falls by detecting patient conditions which may result in a fall. The use of the devices is managed by nursing officers under the direction of a specialist geriatrician. The trial is managed and sponsored by the e-Health Research Centre (<http://www.e-hrc.net>), an Australian government-funded body undertaking ICT research in the health market place.

FALLS PREVENTION

Falls in the aged care community have been a significant problem for many years and often have resulted in either major injury leading to disabilities or fatalities. Falls in older persons with stroke, in particular, have been a large concern mainly because they are managed mostly with medications such as vasodilators, anti-arrhythmic and diuretic drugs. Most of these drugs result in significant lowering of blood pressure, hence resulting in orthostatic or cardiac arrhythmia syncope.

The previous arrangement at the trial site involved no continuous monitoring of patient movement. If a fall occurred, standard practice was to record the incident on a hospital incident monitoring form. Near-falls were not recorded let alone positional sway, and other patient movement. Geriatricians were challenged with the obstacle of information being provided that was late (occurred after the event), incomplete (what was the patient doing prior to the event) or incorrect (errors on data entry). The effort to rectify any of these issues cut into time that could be better spent with patients or other research.

To prevent older persons from falling, aged care providers need to be able to monitor patient movement and activity along with vital signs. The clinical trial is evaluating personal monitoring devices designed to record movement, heart rate and respiration, with the least discomfort to the wearer. Wireless connectivity allows the user to roam, while allowing the care giver access to continuous patient information.

DEVICE SELECTION

An expression of interest (EOI) was called for vendors to submit details of monitoring devices for consideration. The submissions were assessed against the EOI specification and ranked in the following areas:

- data transmission and storage
- sampling rate
- size/weight
- battery life
- monitoring ability
- non-invasiveness
- software compatibility
- conformance to standards
- support and training.

Devices selected for clinical trial evaluation are around the size of a box of cards and contain a printed circuit board, battery, sensors and in some cases a wireless module to transmit data from the device. A laptop with wireless capability is used for data collection and data storage. Devices comply with relevant standards and codes and wireless transmission methods are via established protocols (eg. Bluetooth or IEEE802.11b). There was no desire to connect to other hospital ICT devices or networks.

The types of sensor technology includes:

- accelerometers
- magnetometers
- gyroscopes
- ECG sensors

These sensors are used to directly measure or infer the information shown in Figure 1:



Movement: 	Physiological: 
<ul style="list-style-type: none">•Gait patterns•Fall characteristics•Level of general activity•Postural sway	<ul style="list-style-type: none">•Heart Rate•ECG•Respiration Rate

Figure 1 – Information obtained from personal monitoring of patients.

From movement sensors we can infer gait characteristics, the level of postural sway and imbalance, falls and stumbles can be detected and a daily activity profile can be obtained, indicating times and durations of lying, sitting, standing and walking. Physiotherapists at the trial site have expressed interest in obtaining access to this activity profile to verify the levels of activity claimed by patients.

Physiological sensors provide the following information:

- electrocardiograph (ECG, where information about cardiac cycle can be inferred to determine if significant arrhythmias exist etc.)
- average heart rate
- respiration rate.

Research is also focusing on the most appropriate locations to place sensors (refer Figure 2) taking into account comfort for the wearer, the quality of information gathered from the location and ease of attachment.

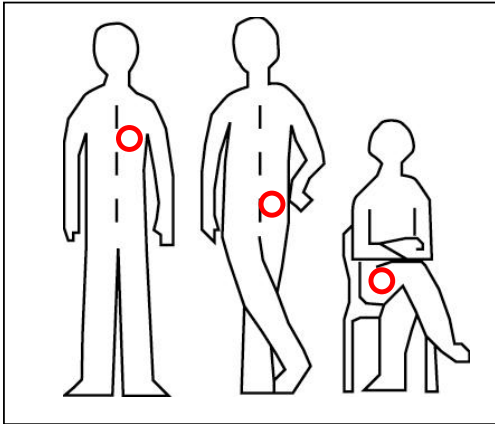


Figure 2 – Possible locations for patient monitor devices

DATA COLLECTION

Data collected from the personal monitoring devices can be either stored on a data card located within the device and downloaded by hospital staff on a regular basis or continuously transmitted from the device to a laptop. There are benefits in wireless transmission for the following reasons:

- Realtime ambulatory monitoring of patient movement data and vital signs.
- Instant and continuous information flow for clinicians who can attend to patients immediately in critical conditions.
- Improved workflow for trial nurses without the need for manual download and transfer data.

There are pressures within health care to minimise error rates, conduct diagnoses on the bases of real time patient data, improve efficiency, and reduce costs. Implementation of the wireless devices proposed in this application is part of the solution to these demands.

Although wireless transmission has clear benefits, there exists reluctance and cautiousness concerning the introduction of wireless devices in clinical environments. Although wireless systems have similar implementation hurdles as other computer systems (eg. reliability, coverage, speed, cost, security, network connectivity), the issue of interference is often a primary concern, as it impacts on performance and patient safety. Misinformation regarding mobile wireless systems, electromagnetic interference and management procedures has led to a broad range of inconsistent policies among healthcare organizations [1]. A balanced approach is needed between overly-restrictive policies that may act as obstacles to beneficial technology and may not address the growing need for personal communication of patients, visitors and the workforce, and the unmanaged use of mobile communications that can place patients at risk.

The remainder of this paper describes the diligence we have applied when ensuring patient safety for the clinical trial of personal monitoring devices. A brief review is provided of studies assessing the impact on wireless interference with medical equipment. We then describe calculations for assessing the impact of wireless interference effects. The paper is concluded with expected outcomes of the trial and future directions.

WIRELESS NETWORKS

Wireless networks for data transmission use a variety of radio frequencies. Table 1 shows some common wireless network protocols and the corresponding radio frequencies. Protocols used in the personal monitoring trial include Bluetooth and IEEE802.11b.

Wireless network	Frequency range
802.15 (Bluetooth)	2.45 GHz
802.11, 802.11b, 802.11g	2.4 to 2.483 GHz
802.11a	5.180 GHz to 5.805 GHz
GPS	1.2276 and 1.57542 GHz

Table 1 – Frequency ranges for common wireless networks; Source: Linux Unwired [2]

Electromagnetic waves transmitted from mobile telephones cause interference with medical electronic equipment [3], and thus prudence would seem necessary when introducing radio wave communication devices in

hospitals. The effect of wireless communication on medical electronic equipment and vice versa, the effect of electronic equipment on wireless communication, has been studied [4-8].

Hanada et al [4] reported zero malfunctions when testing tested 2.4 GHz WLAN against nine pieces of operating medical electronic equipment. However an update of their studies in 2004 using a signal generator to generate higher power (~3W) 2.4GHz signals resulted in the observation of EMI in three pieces of equipment (2 models of syringe pumps & one ventilator) out of ten, with EMI observed at a maximum separation distance of 40cm [5].

Tan [6] tested the susceptibility of 65 devices to both a telemetry system (466MHz/4mW), and WLAN (2.42GHz/100mW). There was no effect with the 466MHz telemetry system, but 2 handheld Doppler units emitted high pitched beating sounds when placed within 10cm of the LAN system (LAN data transmission was acceptable).

Wallin [7] tested 2.4 GHz Bluetooth in a laboratory, operating room and an intensive care unit. 44 electronic medical products were tested for durations of up to 4 hours with no reported EMI problems. Advantages of Bluetooth transmission over WLAN have been reported in that transmitters consume much less power (1mW compared to ~100mW), and that the modules are smaller and less expensive.

The UK Department of Health report on a study assessing EMI at one metre separation for 178 test devices [8]. Computer radio network systems (eg. WiFi systems and Bluetooth) were deemed to cause no significant EMI at one metre separation. Exceptions were GPRS and HIPERLAN (High Performance Radio Local Area Networks) which caused EMI in 4% of medical devices tested.

Considering the above studies, adopting a one-metre separation approach for wireless LAN systems would seem reasonable practice.

WIRELESS CALCULATIONS

This section describes calculations we have performed to quantify patient safety risks from wireless devices that may be present in the environment of the clinical trial. There were two main issues addressed:

- Electromagnetic interference with medical equipment
- Body exposure to electromagnetic radiation

Interference with Medical Equipment

The relevant standard applicable to medical electronic equipment is ANSI/AAMI/IEC/EN 60601-1-2:2001, "Medical electrical equipment—Part 1-2: General requirements for safety—collateral standard: Electromagnetic compatibility—Requirements and tests". This edition incorporates tests for different types of electromagnetic disturbances, and states that equipment must be immune to radiated field strengths of up to 3V/m at frequencies from 80-2500MHz (10V/m for life-support equipment) [9].

So a determination of the electric field from transmitting antennas is required. It is possible to use an electric field probe for local measurement or derive the field strength from the power and distance from the antenna. For accurate measurements of electrical field strength in the near field, where many surveys must be performed, an electrically small sensor is required since large gradients in field components exist and spatial resolution is critical [10].

Thus derived safety levels calculated below may be not as accurate in the near field as those measured with a probe. Three methods are noted in the literature for deriving field strength from antenna power:

METHOD A [11]

$$E = \frac{7\sqrt{P}}{d} \quad \text{(Equation 1)}$$

where P is the radiated power in watts, d is the distance in metres, E is the electric field strength in V/m.

METHOD B [12]

$$S = \frac{P}{4\pi d^2} ; E^2 = 377xS = \frac{377P}{4\pi d^2} \quad \text{(Equation 2)}$$

S = Power flux density [W/m²], P is the radiated power in watts, d is the distance in metres, E is the electric field strength in V/m.

METHOD C [13]

$$\frac{PG}{4\pi d^2} = \frac{E^2}{120\pi} \quad \text{(Equation 3)}$$

where P is transmitter power in Watts, G is the numerical gain of the transmitting antenna relative to an isotropic source, d is the distance of the measuring point from the electrical centre of the antenna in meters, and E is the field strength in Volts/meter. $4\pi d^2$ is the surface area of the sphere centered at the radiating source whose surface is d meters from the radiating source. 120π is the characteristic impedance of free space in Ohms.

In METHOD B the characteristic impedance of free space (120π) is approximated by the constant 377, while in METHOD A, $120\pi/4\pi$ approximated by 72. METHOD C is clearly the more precise derivation of electric field strength and should be used in calculations.

The electric field relation above needs to be corrected in regions near the antenna [10]. This is the region in which the beam is formed, and both the antenna gain and beamwidth vary with the type of antenna illumination and the distance from the antenna. Beyond the radiating near-field region is the far-field region where the secondary pattern characteristics are well defined. The near-field region is that portion of the radiation field lying approximately between λ to $2D^2/\lambda$ from the antenna, where λ is the wavelength and D is the largest linear dimension of the aperture.

For example, considering a 2.4GHz signal, with an aperture dimension of $D=0.25m$:

- Wavelength = (speed of light) / (frequency)
= $(3 \times 10^8 m/s) / (2.4 \times 10^9 Hz)$
= 0.125m
- Near-field conditions exist $2D^2/\lambda$, or 1.0m and closer to the antenna.

Applying no correction (100%) for near-field represents a worst case which is conservatively high in the near-field.

In the calculation of electric field strength, the gain of the antennas are required. The gain or directivity of an antenna is the ratio of the radiation intensity in a given direction to the radiation intensity averaged over all directions. The gain of an isotropic antenna radiating in a uniform spherical pattern is one (0 dB).

From the relations described above, it can be seen that fixed transmitters for radio and TV produce a lot of power but are far away, and generally produce field strengths of less than 1V/m in hospitals. By contrast, the field from a mobile radiating only 2W can be tens of volts per metre at distances of less than a metre. Walkie-talkies and ambulance radios radiate higher power than mobiles, and cordless phones radiate less [9].

For our trial, devices are considered acceptable provided that separations distances calculated from the above relations are observed. Further risk mitigation strategies are being employed such as excluding patients with implantable devices from participation, and not using devices in restricted areas denoted by signage.

Body Exposure to Electromagnetic Radiation

Another patient safety issue to consider with the use of wireless devices is body exposure to electromagnetic radiation. A person's radiation exposure can be measured in several ways. For assessing exposure from transmitters located near the body, the most useful

quantity is the specific absorption rate (SAR). SAR is a measure of the power absorbed in the body (either in a localized region of tissue or averaged over the whole body), expressed in units of watts per kilogram of tissue. Where the transmitter is located away from the body it is permissible to use derived limits, which are easier to measure (eg. W/m^2). A number of organizations have established limits for human exposure to electromagnetic fields, limiting the SAR in the body to safe levels (eg. IEEE, Australian Radiation Protection and Nuclear Safety Agency - ARPANSA). For example, in Australia, allowable limits are 2W/kg spatial peak SAR in the head and torso for the general public [14]. This represents a safety factor of 5 for the general public over the 10 W/kg occupational level. There is no evidence, from laboratory or epidemiology studies, that exposure to electromagnetic energy at levels below recommended limits has any health significance for humans [15].

For interest, Specific Absorption Rate is defined as:

$$SAR = \frac{\sigma E^2}{\rho} \quad \text{(Equation 4)}$$

where E = rms electric field strength [V/m], ρ = density of body tissue [kg/m^3], σ = conductivity of body tissue [S/m] [16]. Relevant values of these properties can be found from various sources on electromagnetic radiation exposure testing (eg. [16,17]).

Frequency	Head conductivity	Body conductivity
450MHz	0.87 S/m	0.94 S/m
1800MHz	1.4 S/m	1.52 S/m
2450MHz	1.8 S/m	1.95 S/m
$\rho = 1000 \text{ kg/m}^3$		

Table 2 – Typical properties of body conductivity and density; (Source: Section 2.2 ACA standard [16]).

From the above table Specific Absorption Rates will be highest for the body (highest conductivity levels) – this is also where the mobile transmitters will be positioned.

Separation distances where SAR values are compliant with the exposure limits were determined for each of the wireless monitoring devices involved with the clinical trial. Minimum separation distances were included in the trial protocol to be observed for the entire time a patient will be monitored in hospital.

OUTCOMES AND FUTURE WORK

Outcomes for this trial are focused in two main areas:

- A formal evaluation of the types of technologies that are best suited for ambulatory monitoring applications such as this.
- Provision of data to provide a basis for further theoretical research into establishing and modeling pre-cursors to falls.

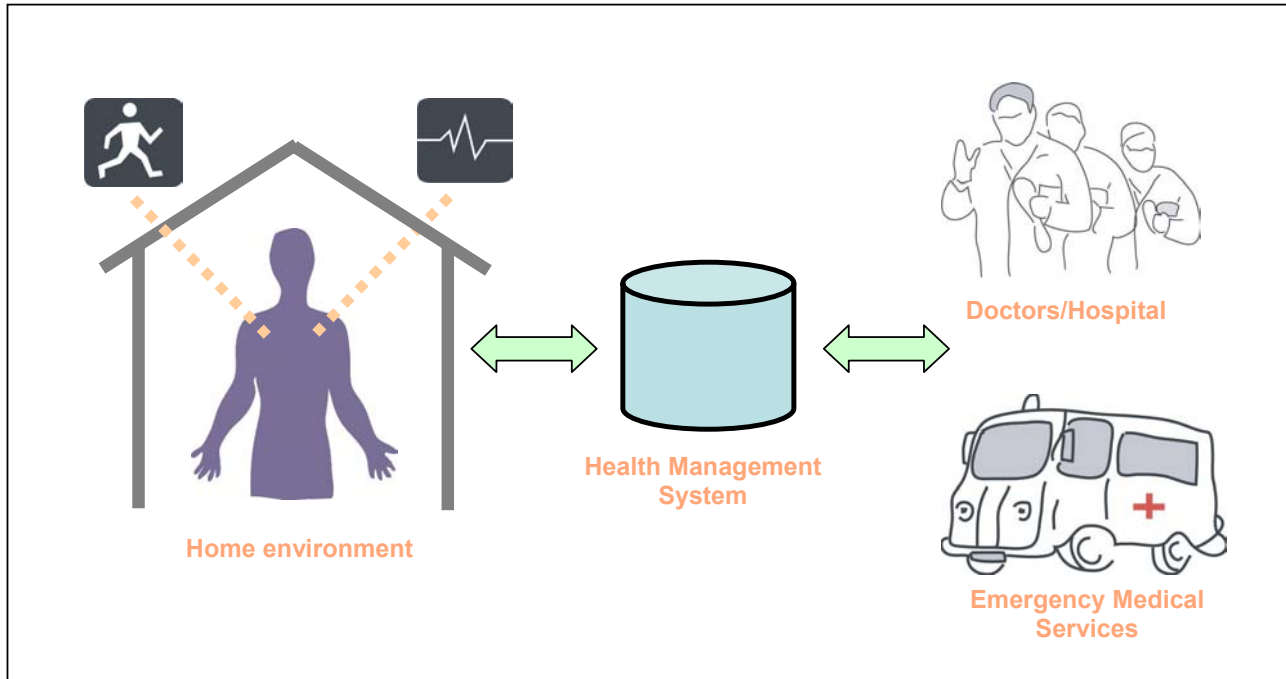


Figure 3 – Future scenarios include linking patient data from home with a health management system, that is accessible by care providers and emergency services.

Future work that is planned may include:

- Subsequent phases of the clinical trial in a hospital environment with wireless devices and real-time monitoring of patients
- Extension of the trials to long-term home-based monitoring of patients

Use of personal monitoring systems with wireless technology will enable real-time, remote monitoring from a home environment. Patient information can be stored in a secure database allowing access by clinicians or carers (Figure 3). Although the wireless market is in its infancy, it has remarkable growth potential (eg. wireless LANS, PANS, networked point-of-care devices). The convergence of the Internet with wireless handheld technologies presents healthcare organisations with excellent opportunities (eg. wireless access to electronic medical records, charts, laboratory results).

CONCLUSION

A clinical trial was described involving sensing patient movement and vital signs, with the intention of predicting and ultimately preventing a fall for patients with a history of falling. The sensor technology was briefly described along with methods of data collection. The benefits of data transmission via wireless methods was discussed along with the perceived reluctance to embrace wireless applications in health care. To provide evidence of safe implementation of wireless devices, we provided a brief review of wireless interference assessments and detailed our calculations which were applied to quantify safety aspects. Health care organizations implementing similar wireless monitoring may benefit from this description.

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