

# The dangers of listening to the fetal heart at home

An over the counter fetal heart monitor can be a fun purchase for expectant parents eager to hear their unborn child. But **Abhijoy Chakladar** and **Hazel Adams** warn that parents shouldn't rely on the devices to indicate fetal health

**T**he fetal heart rate is commonly measured on the labour ward and during pregnancy to monitor the health of the fetus. It requires training and skill to perform accurately.

Over the past few years fetal heart monitors have been marketed to expectant parents who want to hear their baby's heartbeat. However, if not used properly these devices can provide false reassurance, as our recent case describes.

A 34 year old woman presented urgently to our labour ward on a Monday unable to detect her baby's heartbeat with her fetal heart monitor. She was 38 weeks pregnant with her first baby and was fit and well, with no medical history. Screening blood tests, fetal anomaly, and subsequent growth scans had shown no abnormalities. The preceding Friday she had noticed a reduction in fetal movements but had reassured herself by listening to the "fetal" heartbeat over the weekend. An urgent ultrasound scan showed no fetal heart activity and intrauterine death was diagnosed.

We assumed the patient had been listening to her own pulse or placental flow. We found no reason for the stillbirth. All blood tests and infection screens from the mother gave normal results. There was no significant microbial growth from the placenta or fetus, and the fetus seemed morphologically normal. Histopathological analysis of the placenta found nothing unusual.

There has been another recent case of false

reassurance with a home fetal heart monitor.<sup>1</sup> Although the baby did not die, it required a long stay in the neonatal intensive care unit and had serious neurological morbidity.

## Marketing claims

After the experience in our obstetric unit, we conducted an internet search and were surprised by the number of fetal heart monitors available. There are two main types: sound amplifiers and Doppler ultrasound devices. A high street pharmacy and a large toy retail chain stock a prenatal listening (amplifying) system that claims to be "easy and safe to use to hear your unborn baby's heart beat."

However, without training the sounds detected could easily be misinterpreted. Although potential purchasers on the pharmacy's website are cautioned that "it is not a medical device and should not replace medical supervision," the toy chain's website gives no such advice. Other internet retailers are not so reserved ([www.dopplerhire.com](http://www.dopplerhire.com)), suggesting that Doppler devices can be used for reassurance in between hospital visits and scans. The safety of the Doppler ultrasound devices is stressed, in that they do no harm to the baby, but the risks of delaying seeking medical attention and the limitations of Doppler devices tend to be overlooked.

## Current practice

Movements can vary considerably from fetus to fetus and at different times of the day. A recent Cochrane review noted that



there was not enough published evidence to support fetal movement as a marker of fetal wellbeing.<sup>2</sup> Nevertheless, our obstetric unit, like most, encourages expectant mothers to present to the labour ward for assessment if fetal movements reduce.

The normal fetal heart rate ranges between 110 and 160 beats per minute with a baseline variability of 5 beats per minute. On the labour ward, the fetal heart rate is usually measured over time with an electronic fetal monitor, which gives a paper trace, and is interpreted by experienced midwives and obstetricians. Any decisions on fetal health are made only after taking careful histories of the events leading to presentation, examination, and consideration of the wider clinical context. Home monitoring devices can give only a snapshot of the heart rate and provide no indication of other important prognostic features.

## Moving forward

The intrauterine death in our case may have been unavoidable, but the use of a fetal heart monitor certainly delayed presentation to hospital. Manufacturers and retailers have an obligation to make the limitations of these devices absolutely clear, as the untrained use of fetal heart monitors constitutes a risk to the safety of pregnant women and their unborn



babies. The risk will undoubtedly increase as these devices become more popular. The use of home monitors may also result in women unnecessarily referring themselves to general practitioners and obstetric units when they cannot hear the fetal heart because of inexperience. We asked the retailers how many devices they had sold or hired out but received no reply.

Obstetric services need to educate expectant mothers about the limitations and the potentially fatal consequences of untrained use of fetal heart monitors and to present clear guidance about when to seek medical review.

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**Patient consent obtained.**

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## FROM WARD TO HIGH STREET

Home fetal heart monitors have become widely available in recent years and cheap enough for big UK retailers such as Mothercare to market the devices as one of the “pregnancy essentials.” The Medicines and Healthcare Products Regulatory Agency, which is responsible for those fetal monitors that are categorised as medical devices, said it had concerns these products were being increasingly used by lay people. A spokesperson for the agency said: “We are aware of a case where a mother, concerned by lack of fetal movement, was reassured by an apparent fetal heartbeat from her monitor. However, it appears that the monitor was reacting to the maternal heartbeat and the child was later stillborn.”

The agency said it can take action when fetal monitors do not comply with UK and European Union regulations on medical devices and aims to remove them from the market. But the spokesperson added: “However, these devices are often sold over the internet from sources outside the UK, and often the EU, and it is difficult to control such sales.”

The agency cautions that consumers should buy only CE marked fetal monitors for home use and even then be careful. “While monitors are widely used by health professionals, they will have been trained for their use. They will also have access to additional methods of assessing the health of the fetus. Members of the public are unlikely to have the necessary knowledge or experience to use the device effectively at home.”

Some of the monitors on the market are medical grade ultrasound Doppler devices, which have to conform to European medical

directive 93/94/EEC and be approved by the US Food and Drug Administration. They typically retail at £70-£90 (€76-€98; \$114-\$147) and are manufactured by professional equipment producers. Cheaper are the non-ultrasound devices, such as the Summer Infant Prenatal Listening Device, which retails from £20. These are not considered medical devices—and are marketed as listening devices rather than heart monitors—and therefore are judged against much lower general product safety regulations.

Sue Jacob, a midwife and spokesperson for the Royal College of Midwives, said the availability of such products was of concern to members: “There seems to have been a rise in these commercial products over the last 18 months, including blood glucose testing kits, and blood pressure monitors. But who is approving these products?”

Donald Peebles, speaking for the Royal College of Obstetricians and Gynaecologists, said it was of concern if, after a change in fetal movements, mothers didn’t seek medical help but instead relied on home heart monitors for reassurance. But if an anxious patient sought medical advice before purchasing or renting a monitor and had some element of training in how to use one by qualified staff, they could be of some use, he added:

“If used under medical guidance, these devices can be useful. People who have had a previous stillbirth can be very anxious and if they haven’t felt their [unborn] baby move for short periods of time then hearing the heart beating can be reassuring.”

A *BMJ* article in August by an obstetrics team at Wirral University Teaching Hospitals NHS Foundation Trust said: “In untrained hands it is more likely that blood flow through the placenta or the maternal aorta or iliac vessels will be heard.”<sup>1</sup> The trust now has posters in its antenatal areas recommending that women do not use these devices.

Rebecca Coombes associate editor, *BMJ*, London  
 Complaints about non-ultrasound devices should be made to a local trading standards agency. Adverse incidents involving medical devices can be reported to the Medicines and Healthcare Products Regulatory Agency through the hotline 020 7084 3080.

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# An eye on profit

With its income from private patients approaching government limits, Moorfields is one of the foundation trusts hoping that the recently announced review will lead to relaxed rules.

**Jonathan Gornall** reports

Dubai, sun baked second city of the oil fuelled United Arab Emirates, glitzy home to the world's tallest building, largest shopping mall, and two gigantic manmade islands created in the shape of stylised palm trees, is an unlikely setting for an ideological battle over the future of the National Health Service. It is certainly a long way from City Road, London, but here, on the 370 000 m<sup>2</sup> campus that is the world's first medical free-zone—a tax and customs duty-free oasis in which 100% foreign ownership is allowed—can be found a bustling branch of Moorfields Eye Hospital, the first such overseas outpost and example of an entrepreneurial spirit that, depending on viewpoint, could either rescue or ravage the NHS.

Many in the NHS are watching with interest to see how the pioneering Dubai venture pans out; two years in, it has yet to make a profit but is ahead of its business plan and on target to do so. Under current legislation, the success of such schemes is limited by the cap on the percentage of total income foundation trusts can earn from private patients, but last week the government committed to a rapid review of the law that could change the rules. If this happens others may be tempted to follow Moorfields' lead.

The private charges cap was introduced in the 2003 Health and Social Care Bill to appease concerns that the introduction of



foundation trusts would lead to a two tier NHS. The bill eventually squeezed into law by just 17 votes by limiting the amount of income a foundation trust could earn from private patients to the percentage of the total earnings it had from this source in 2002-3.<sup>1</sup>

## Branching out

Moorfields, one of the first foundation trusts to be created, opened its outpatient branch in the brand new Al Razi building in Dubai Healthcare City in July 2007. Its 80 or so



neighbours range from the Mayo Clinic, Boston University Institute for Dental Research and Education, and Harvard Medical School to the American Academy of Cosmetic Surgery Hospital, the Swiss Academy of Scientific Acupuncture, and the California Chiropractic Center.

Moorfields' staff of almost 30 in Dubai includes four consultants specialising in glaucoma and retinal, corneal, and oculo-plastic disease. There are three operating theatres, including a laser in situ keratomileusis (LASIK) suite for refractive surgery. The project is led by Chris Canning, who has a triple role as managing director, medical director, and practising consultant and moved to Dubai in 2006.

When the plans emerged at the end of 2006, the UK press dutifully attacked them, the *Daily Mail* claiming, wrongly, that the trust had borrowed £6m (€6.6m; \$9.8m) and that "badly needed" consultants and other NHS staff were being offered "lucrative packages to abandon their UK posts." It was, Labour MP Jon Trickett told the paper, "an outrage that this is being allowed to happen."<sup>2</sup>

In fact, capital costs were kept low through leasing rather than buying and the entire financial burden of the Dubai operation has been borne by the profits from Moorfields' private operations in the UK.

"The losses we have made in Dubai are not



**Offshore accounts: will opening outlets overseas, such as Moorfields Dubai (left), help boost the private income of NHS Foundation Trusts, such as Moorfields London?**

that since 2003 has grown its private-patient activities at a faster rate than its overall income will have to revert to the level they were at in 2003 in order to become a foundation trust, which doesn't seem to make a great deal of sense."

Moorfields is considering expansion into the neighbouring capital emirate of Abu Dhabi, where it already holds clinics twice a week at the Imperial College London Diabetes Centre. It is, says Mr Pelly, "a numbers game"; Dubai, Moorfields has discovered, is not a sufficiently large pool to make large surpluses. It has also found a cultural difference in the conversion rate from outpatient consultations to surgical operations, which is where the money is. In a medical system that lacks the equivalent of a general practice gateway, "what we've learnt is that typically an individual will get three or four opinions before deciding where to go for surgery."

All things being equal, Mr Pelly believes there is no reason why other foundation trusts shouldn't follow Moorfields' example, provided they "make sure they do their homework well, partner with the right people and have a strong domestic and international brand to start with."

The only other NHS name in the region at present is Great Ormond Street Hospital, which since January 2006 has operated a referrals office in Dubai manned by a team of four, including a nurse adviser, whose role is to help families who need to travel for treatment in London. Since it opened, 456 patients

have passed through the portal, which the hospital says costs it about £230 000 a year to run. In the first year of operation, private income increased by £600 000.

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#### Effect on NHS services

Whether other trusts follow the Moorfields model now depends chiefly on the government's ability to resolve an ideological struggle that has been raging ever since the conception of the foundation trust in 2003. For the past two years UNISON, the public service union, has been fighting a battle with Monitor over its interpretation of the law governing the cap, as set out in its reporting manual for NHS foundation trusts.<sup>4</sup> In September 2007 it warned that unless Monitor tightened its guidance it

coming out of UK tax-payers' money," said John Pelly, who joined Moorfields as chief executive in April last year. "The significant profits we are making from our UK private operation and Moorfields Pharmaceuticals are bearing the costs of the Dubai operation until it starts to turn a profit, and they exceed the losses Dubai is making."

#### Restricted profit

Moorfields' private earnings cap is 13.74% and, as private income forms an important and growing proportion of the trust's overall earnings, if the cap restrictions aren't lifted it won't be long before this could pose a serious problem. Earnings in Dubai last year were about £800 000 higher than expected by the business plan. "Each year we have done better than our plan," said Mr Pelly, "and though we are not yet making surpluses we are rapidly heading in that direction."

In 2008-9, Moorfields' total patient related income from all sources, including £78.8m from the NHS and £6.1m from Moorfields Pharmaceuticals, was £96.31m; £11.32m of this, including £2.4m from Dubai, was from private patients, meaning the percentage of private income was 11.75%. The hospital was within £2.2m of breaching its cap.<sup>3</sup>

When the Dubai plan was first discussed, said Mr Pelly, "the expectation was that because it was overseas private income it

would not count against the private income cap. In the event, Monitor [the body that regulates foundation trusts] decided that it should count and so from day one we were caught by that. We are operating within our cap so it's not an issue at the moment, but we will need to think very carefully about what to do if Moorfields Dubai or indeed our UK private operation grows significantly faster than our total patient related income, as it may well do."

For him, the cap is, "frankly, absurd . . . To constrain our ability to generate private income and surpluses in a world in which the core public sector funding is going to be declining in real terms seems unwise. We believe that there is more that we can earn in terms of non-NHS income streams, but if we are going to find ourselves bumping up against the cap then we are going to have to forgo those opportunities, which seems a shame for us and the wider NHS."

In addition, said Mr Pelly, the current regulations place a perverse hurdle in the way of any NHS trust seeking foundation status: "The government views foundation trust as being the best model for healthcare delivery in the UK, and it's the government's declared intention that all NHS providers will in due course become foundation trusts. Yet an organisation

would seek a judicial review. Monitor compromised, and in December 2008 announced that all income from joint ventures where the foundation trust was not in overall control would also come under the cap.<sup>5</sup>

It wasn't, however, enough to satisfy UNISON, as Karen Jennings, the union's head of health, made clear shortly afterwards. For many MPs, she said, the "safety net" of the cap had been "the decider on which way to vote . . . put there to ensure that NHS patients were not pushed to the back of the queue and seen as the poor relations to paying patients." UNISON would press on with its judicial review.

Evidence that seemed to support UNISON's concerns emerged in July 2008; an independent analysis carried out for Monitor showed that in 2007, under a strict interpretation of the rules of the statutory cap, 40 trusts had under-declared private income by a total of £70m.<sup>6</sup>

The judicial review has now been listed for hearing on 2-3 November, but after an announcement by the government on 12 October of its own review of the cap, whatever decision is reached in the courts may prove irrelevant.

The government's decision was prompted by a probing amendment to the Health Bill, sponsored by the Foundation Trust Network and introduced during its passage through the Lords in May by Baroness Meacher, chair of a mental health foundation trust in east London. It would, Baroness Meacher told her fellow peers, have kept the "illogical and unhelpful" cap in place while allowing the government to make exceptions to the rule. Relaxing the cap, she said, would "enable the NHS to benefit from the considerable export opportunities provided by our highly respected NHS clinicians. We can ill afford to squander that opportunity."<sup>7</sup>

The amendment was withdrawn, however, and a statement by Mike O'Brien, the health minister, during a debate in the Commons on 12 October made clear why. The government, he said, intended to carry a full but rapid review of the cap, with a view to seeking feedback from stakeholders by January and developing firm proposals by the spring.

"People have differing views about the

private patient cap," he said, and securing a consensus would not be easy: "Some say that there should not be one, some say it should be at zero, and there are a variety of views in between."

Nevertheless, the government's view was that the current system "is not fair . . . there is a strong case for reform" and, while it was committed to "maintaining and strengthening

the protection of NHS services for NHS patients first," it wanted to allow foundation trusts "a degree of flexibility . . . We

want to ensure that any private money that goes into the health service is directed in the best interests of the patients and the NHS as a whole."<sup>8</sup>

Reading between the lines, a relaxing or even a scrapping of the cap seems possible in the new year—provided the government can find a way to reassure those who suspect a creeping privatisation of the NHS.

Dave Godson, the national officer in UNISON's health group with responsibility for foundation trusts, said if the government's review "decided it was going to be stipulated that all private income must be invested into NHS services then clearly we would have to consider our position in the future. But at the moment our understanding is that the majority of money has been reinvested into developing private income services, and that isn't something we can support."

UNISON remained determined, he said, "to protect an NHS that is free at the point of access for all people. If we keep going down the route of private patients we will get a two tier service, which we cannot support."

The union is also not impressed by the argument that, at a time when trusts are facing budget cuts, private income is more essential than ever for the NHS.

"I'm not sure the anecdotal evidence supports that," said Mr Godson. "In a time of recession what seems to be the case is that the number of people accessing private care declines. There is also no evidence at the moment to support the suggestion that money generated by private income has been put back into the NHS; it has been ploughed into the further development of private income services."

Not so, says Sue Slipman, director of the

NHS Confederation's Foundation Trust Network. Trusts "marry their public service ethos with commercial and entrepreneurial approaches to deliver benefits for NHS patients" and all are "fully committed to the NHS. Any commercial activity they carry out that is caught by the cap is aimed at directly benefiting NHS patients."

The governance structure for foundation trusts, with governors elected by members drawn from the local community, staff, and patients, meant that boards were held to account on major spending plans and decisions, she said. "Any surplus made is reinvested in services and innovations that benefit NHS patients."

Furthermore, "In a time of recession, with a possible £20bn shortfall in NHS funding, the ability to lever in additional funding and resources using joint ventures and partnerships, as well as other private-patient activity, has to bring dividends. Supplementing NHS resources doesn't only benefit NHS patients, it could also contribute to saving NHS jobs."

It was clear, she added, that the Foundation Trust Network had won the debate about the cap in the Lords. Now, "We will hold the government to its commitment to review the issue. Clearly we need to see swift action as the predicted NHS recession is nearly upon us."

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See **NEWS**, p 1105