reviews

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This World: Bad Medicine

BBC 2, Tuesday 12 July at 9 pm

Rating: ★★★☆

This piece of investigative journalism covered the massive worldwide trade in substandard drugs and the harm that these do. Nigeria was the focus, but I suspect that the programme could have been made about almost any developing country.

The context in which this scam flourishes is one of, firstly, widespread failure to contain major killers, most notably infectious diseases such as malaria, tuberculosis, and HIV; secondly, personal and national poverty; and thirdly, underdeveloped regulatory systems.

Malaria and tuberculosis are both curable, and HIV can be contained by drugs, and people the world over have the right to expect standards of quality, efficacy, and safety. Tablets must contain the specified mass of the active ingredient, must not contain more than (defined) traces of contaminants, and must be bioavailable. Furthermore, the efficacy and safety of a drug must have been shown as part of rigorous clinical trials before the drug is launched. Legislation around these basic principles has evolved over the centuries but has most recently been enshrined by the International Conference on Harmonisation (www.ich.org), which has established inter-

nationally agreed standards for good manufacturing practice, good laboratory practice, and good clinical practice.

This World: Bad Medicine dealt mainly with good manufacturing practice but also ventured into the area of generic drugs fraudulently packaged with the proprietary details of multinational drug companies. It is expensive to develop new drugs, and development carries major financial risk, so multinationals protect their investments by protecting their patents. Once the patent lapses, generic companies can legally start to manufacture the drug but must, of course, prove drug quality and use their own packaging.

Some of the programme's examples were probably drugs of acceptable quality, masquerading as Pfizer or Merck products. Not so bad, you might think (except for Pfizer or Merck), but the programme revealed the temptation to include in drugs less and less of the expensive medicine, right down to straightforward frauds that contained no active drug at all. Obviously, such "placebos" carry grave risks (one of the tragic examples being a drug-free "adrenaline" used during cardiac arrest after surgery). But all substandard tablets carry some risks: therapeutic failure and the development of microbial resistance, as a result of underdosing, or toxicity, as a result of chemical or microbial contaminants.

The programme focused on Nigeria, as the victim, and on India, as the home of most of the offenders, and featured a large helping of undercover filming. For Nigeria one could have substituted most countries of sub-Saharan Africa beset with overwhelming health problems and chronically overstretched budgets. Budgets are now stretched all the more because previously inexpensive drugs (such as chloroquine for malaria) have failed, and their recommended replacements (such as Coartem—a combination of artemether and lumefantrine) are much more expensive. This is fertile ground for hospitals to try to make savings by buying drugs from local suppliers (which seems to have been the case with the supply of "adrenaline" used so catastrophically after paediatric cardiac surgery). Gangsters, of course, are not difficult to find anywhere on this godforsaken planet, but the combination of massive profit and underdeveloped systems for government scrutiny makes African countries an obvious honeypot.

One aspect of drug use in Africa did not receive prominence in the programme, and it is worth stressing now. A drug might legally be "prescription only," but in practice

it will almost always be sold without prescription by small scale retail outlets. Thus drugs that ought to be used under close medical scrutiny are often available for use at home, without even a diagnosis in many cases: the opportunity for drugs to cause harm in Africa is alarming (*Clinical Microbiology Reviews* 2004;17:612-37), even before aspects of quality are taken into account.

The programme was not forthcoming with many answers, but solutions are not difficult to see. People, wherever they are, should be using drugs that are guaranteed by robust national quality control systems in a setting of close regulatory scrutiny (including pharmacovigilance programmes, especially for new drugs). However, good quality drugs cost much more than substandard alternatives, while robust regulatory systems are extremely expensive and must sit on a foundation of accountable and transparent governance.

It is clear the programme makers did not really admire multinational drug companies any more than the counterfeiters did, but people need to accept that one cannot have it both ways. Generally, only multinational companies have the financial and technical resources to discover and develop new drugs (although it should be pointed out that the outstanding Indian company Ranbaxy has discovered and is developing a new anti-malarial); and the consumer must cover the costs of this work, perhaps with help from international donors such as the Global Fund for AIDS, Tuberculosis, and Malaria.

Meanwhile, it would be an understatement to say that establishing decent governance in developing countries (surely the necessary foundation for so much) is a major challenge. The G8 nations say that they want to help countries to develop such systems: time will tell whether they mean it and whether they are up to the challenge.

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Competing interests: PW is the chairman of two product development teams for the World Health Organization's special programme for research and training in tropical diseases. The partners include Medicines for Malaria Venture, the UK Department for International Development, and GlaxoSmithKline. GSK Pharmaceuticals has made educational grants to audited accounts within the University of Liverpool, to which PW has access.

Items reviewed are rated on a 4 star scale (4=excellent)

Fake drugs: coming to a pharmacy near you?

PERSONAL VIEWS

The London bombings: a hospital doctor's experience

I work as a cardiology registrar at University College London Hospital. On Thursday 7 July 2005 I started a ward round at 8 am. Towards the end of this round we were interrupted by an announcement that the hospital had just gone on to major incident alert, as "four bombs had gone off and multiple casualties were expected." Our reaction to this news was initially shock and disbelief, but as soon as the staff realised the enormity of what had happened they all did everything they could to help.

Senior medical staff quickly and proficiently assessed every patient on the medical wards, and all stable patients were taken to our sister hospital, the Middlesex. Porters and nurses worked together, helping patients from beds to wheelchairs; and ambulances transferred patients across to the other hospital in a carousel fashion. The receiving doctors accepted patients without question and efficiently reviewed each and every one to ensure safe ongoing treatment.

The unspoken realisation that these people were the supposedly "lucky" ones strengthened our resolve to do everything we could

At our hospital senior members of staff started coordinating the receiving units. I was amazed by how many people turned up to help: nurses who were off duty came in; doctors on holiday and on night shifts returned. Non-clinical research fellows abandoned their experiments and came to offer their services. Healthcare assistants, medical and nursing students, physiotherapists—every member of hospital staff turned up to lend a hand in any way they could. Nurses and doctors from elsewhere who happened to be in London came to offer their help. While I was in the accident and emergency (A&E) department I answered a ringing phone: it was an off-duty GP calling from west Suffolk, asking if he could help. Many more medical professionals made similar phone calls offering their services. Many had even taken taxis and travelled long distances and for many hours to offer a helping hand. There were stories of taxi drivers refusing to accept payment, of local caterers who brought in refreshments for staff, of members of the public wanting to donate money there and then.

The A&E department was full of doctors, from all specialties. Ophthalmologists came from Moorfields Eye Hospital, neurosurgeons arrived from the Institute of Neurology in Queen Square, and cardiothoracic surgeons came over from the

Heart Hospital—experts from local centres offering their skills in this time of need. Entire teams of surgeons were waiting to help: maxillofacial surgeons, ear, nose, and throat surgeons, plastic surgeons, orthopaedic surgeons, and many more. Paediatricians, obstetricians, gynaecologists, psychiatrists—every specialty in hospital medicine was there in force. Radiologists were there with ultrasound machines, running from patient to patient. The computed tomography scanners were constantly on, and patients were ferried through the scanners one after the other, a radiologist reporting the scans as they appeared. The physicians were also there—not just clinicians but every research fellow and non-clinical physician in the trust. However, we still felt very helpless as all the trauma patients began to roll in.

The first patient had had a leg blown apart, requiring a traumatic amputation above the knee. Many nurses and doctors were in tears, and the atmosphere was grim. The sense of anger and frustration was palpable. The unspoken realisation that these people's lives would never be the same again, and that these were the supposedly "lucky" ones, strengthened our resolve to do everything we could as well as we could.

I was humbled by everyone's team work, not just among the clinical staff but also in the efforts of those working away from the direct care of patients, such as the caterers making sure everyone had a sandwich and cup of tea, the ward clerks busy taking blood samples to the labs, and the cleaners, who spoke little English, silently and efficiently emptying the bins. I was struck by the calmness shown by everyone as they worked to the best of their abilities. Even when the mobile phone networks went down, and communication with loved ones was lost, no hint of frustration was seen, just an acceptance of the situation and a silent determination to continue with the job until circumstances improved.

Some distance from the chaos in A&E, physicians were also working hard. The intensive treatment unit had discharged semi-stable patients to the wards so that trauma victims could be received. We worked round the clock trying to stabilise very sick patients who ideally merited intensive treatment. But every patient had at least one dedicated nurse, many of whom had come in voluntarily to help out and some of whom didn't even work at the trust. And every four patients had a medical registrar or consultant, many of whom had given up their spare time to be there. Psychiatrists and psychologists offered their services through the night to help victims come to terms with what had happened.

We spent the next day addressing the secondary problems that followed the chaos. Psychological support was crucial. Many members of staff attended the debriefings that were offered. Issues remained to be dealt with, such as providing hepatitis B immunisations to victims who had pieces of their fellow commuters blown into them.

I have never been more proud to be both a healthcare professional and a Londoner

I worked solidly from morning to evening, and I know many of my colleagues did much, much more. I know that things would have been a lot worse were it not for the professionalism and goodwill of everybody who helped. I was sickened by what happened but at the same time humbled by how willingly people pulled together to offer what they could. I have gained a new respect for human nature.

In a time of crisis people in London selflessly gave up their time and money and offered whatever support they could. Staff in the hospital worked calmly and efficiently, with gritty resolve, displaying flawless team work as they employed their individual skills. I am honoured to work with such wonderful people. It is a day I will always remember, not just because of the scale of pointless suffering but also because I saw how healthcare professionals and complete strangers united to help. In the eight years since my qualification I have never been more proud to be both a healthcare professional and a Londoner.

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“Are there any doctors here?”

As soon as I heard the bang, I knew it was a bomb. Thunder doesn't sound that brutal or shake the building like that. At the time I was in a meeting room in BMA House with a visitor to the *BMJ*. “That's a bomb,” I said, as my visitor and I leapt from our seats and ran out into the main editorial office. Everyone was rushing to the balcony to see what had happened. Even before I got close to the edge I knew from the contorted expressions etched into the faces of my friends and colleagues looking down on to the street two floors below that it was something horrific. Some of them were wailing. I peered over the edge for an aerial view of a most sickening scene. The roof of the crippled bus—the number 30 that was destroyed in a terrorist attack in Tavistock Square last week, right outside BMA House—had been ripped off like the lid of a sardine tin. Debris, bodies, and body parts were strewn across the road. In the eerie, smoky silence, a few people wandered in the street, dazed and bloodied. Our ordinary, leafy London square had become a battlefield. None of us could bear more than the briefest of glimpses.

We didn't need a fire alarm to tell us to get out fast. The first instinct was to get away from any danger. Afraid and nauseous, heart pounding, I escorted my visitor down the fire exits to the back of BMA House. Among the relative safety of the crowd now gathering at the rear of the building, it dawned on me that as well as being a frightened editor and family man I was also a doctor. Of sorts. A former general practitioner to be precise, several years out of practice and not registered with the General Medical Council. Shouldn't I be helping? Could I really help?

Before I could make the decision to roll up my sleeves, it was made for me. “Are there any doctors here?” yelled a woman with a walkie-talkie and a fluorescent yellow jacket. “Yes, here,” I barked back automatically. Somehow three injured women had staggered from the scene of the blast to the

back of the building. A colleague (another former doctor), my visitor (a junior hospital doctor), and I set to work.

I made straight for a young woman soaked in blood from a head injury. Someone handed me a first aid box. In an instant, my 12 year old memories of accident and emergency came flooding back. It was the metallic smell of blood and the whiff of my latex gloves that hit me hardest, but the trauma basics and roadside manner seemed almost as hard wired. I'm still rubbish at bandages. After my best attempt at a systems check without any equipment, we escorted our walking wounded back into BMA House and helped to clear a large lounge (the Hastings Room) into a makeshift receiving room. With our patients shocked but stable, we turned our attention to the courtyard of BMA House and the mayhem in the street beyond.

My 12 year old memories of accident and emergency came flooding back

Small clusters of doctors and paramedics were crouched over several serious casualties who had been carried into the courtyard on improvised stretchers. Many already had intravenous drips and stabilised cervical spines. Some were writhing in pain. Others looked ominously still. Doctors of all pedigrees were there—a group of GP trainers here for a meeting, BMA committee doctors, doctors on the staff of the BMA and BMJ Publishing Group, and some others I didn't recognise, who I think were from nearby hospitals. Many had been working bravely on the front line in Upper Woburn Place, the street that runs between Euston Station and Tavistock Square along which the bombed bus had been travelling.

It seemed clear who was in charge round each casualty, and although there were many weary looking faces, there was a wartime spirit, determined and supportive. My role now was as human drip stand, bag changer, stretcher bearer, patient comforter, log roller, and wound dresser. In the Hastings Room patients were prioritised efficiently and shipped out as soon as the ambulances were ready.

It seemed like an age, but it was only about two hours since the cruel blast and it was time to clear up. We couldn't use our mobile phones in the early stages; now, finally, was the time to be a family man again and phone loved ones at home to tell them that I was safe. Not everyone was so lucky.

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Another personal view relating to the bus bombing outside BMA House is available on bmj.com

SOUNDINGS

Music of the mountains

Armenia once stretched from the Black Sea to the Caspian, but these days it is small, high, and landlocked. Its capital, Yerevan, looks wistfully across a valley to Mount Ararat, last resting place of Noah's Ark and now part of Turkey. “But only temporarily,” they say in Yerevan's marketplace.

The country's population is three million, but with its troubled history there are more Armenians in the diaspora. Many of them are musical. Charles Aznavour was born Charles Aznavourian in Paris. Cher, famed for her minimalist gowns, began life as Cherylyn Sarkisian in California. Aram Khachaturian, best known for his “Sabre Dance,” lived in Moscow but Yerevan Opera House has an auditorium named after him.

Its favourite opera, Tigranyan's *Anoush*, is a story of doomed love in a mountain village. The male chorus wear shaggy coats and hats, and the heroine throws herself off a cliff in the last act. Just the thing, we thought, for pre-conference relaxation.

Opera-going in former Soviet countries is a family affair. We found ourselves sitting in front of middle aged mums who exchanged observations during most of the performance. They fell silent in the tenor's final scene—not when the poor man was fatally shot by the bass but when the crowd parted to reveal his mother. Behind us there was dead silence, then sniffles.

In front of us was a group from the diaspora, just flown in from the West and checking out their heritage.

After the conference, there was time for a short trip to a mountain monastery. Armenia adopted Christianity in 301 AD, and church building has been a national preoccupation ever since. This one nestled against a cliff and merged with a series of chambers hewn from the rock, complete with pillars that had survived several centuries and one major earthquake.

As we marvelled, the sound of a choir echoed around us. We lowered our digital cameras respectfully. The singing seemed to come from another world. Back at the altar we saw in the candlelight a young woman—head bowed, lips barely moving—murmuring a psalm. The mountain was supplying the harmonies. Nice to know that the diaspora does not have all the best tunes.

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