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Flawed and Poor-Quality Surgical Instruments Place Patients at Risk

Analysis by Dr. Joseph Mercola | September 14, 2024

STORY AT-A-GLANCE

- Surgeons need the right tools for the job, and these tools must be made to exact specifications and be of the highest quality. A BBC investigation reveals 20% of all surgical tools used fail to meet quality standards
- Common defects include fractured and re-welded instruments, sharp protruding guide pins on forceps that lacerates gloves, burs and metal fragments that break off, corrosion and pitted metals
- Two-thirds of the world's surgical instruments are manufactured in Pakistan, although many are marked "Made in Germany" — either through a legal loophole or an illegal profit-boosting scheme

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The BBC documentary, "Surgery's Dirty Secrets," which originally aired in 2011, investigates the sources of surgical tools, and highlights flaws in British safety regulations. If you're like most, you probably assume that surgical instruments are made to the very highest, exacting standards. But the reality of where and how these tools are made is downright shocking.

According to BBC reporter Samantha Poling, who spent a year investigating this topic, there are significant problems in the industry — problems that can, and have, caused severe illness and death.

An estimated 30 million operations are carried out in British hospitals each year. In order to perform, surgeons need the right tools for the job, and these tools must be made to exact specifications and be of the highest quality.

Poorly made or non-functioning surgical tools can mean the difference between a successful surgery and the loss of a limb or organ, or death of the patient. For example, for each fraction of a second a surgical assistant is struggling with a poorly functioning arterial clamp, the patient is losing blood, compromising the success of the surgery.

Lethal Infections Spread by Surgical Tools

In 2009, Dorothy Brown underwent heart surgery at Nottingham City Hospital. While the operation was a success, she contracted an antibiotic-resistant infection that nearly claimed her life. Ten other patients operated on by Brown's surgeon around the same time contracted the same lethal infection.

Five of them subsequently died. In the U.S., at least 1,500 incidences where poor-quality surgical instruments have caused harm each year.[1]

A confidential report obtained by Poling reveals the two most likely causes of the mass infection at Nottingham City Hospital were either airborne bacteria or micropunctures in the surgeon's gloves. As a result of the internal investigation, surgeons must now wear thicker gloves or double-up on regular gloves.

But what would repeatedly cause micropunctures in the surgeon's gloves in the first place? According to experts, the most likely cause is poor-quality surgical instruments.

While few medical professionals were willing to go on record with the BBC, Tom Brophy, a lead technologist with Barts Health NHS (National Health Service) Trust, did. Deeply concerned about what he's been seeing, he has started collecting evidence showing just how defective some surgical tools are.

Most of these defects cannot be seen with the naked eye, but under magnification, jagged edges and poor-quality construction becomes readily evident. Common

problems reported by Brophy include:

- Fractured and re-welded instruments, which harbor and spread bacteria
- Sharp, protruding guide pins on forceps that lacerate gloves
- Sharp burs and metal fragments that break off, lacerating gloves and/or pose an infection risk if deposited inside the patient
- Corrosion and pitted metals that pose an infection risk
- Faulty screw heads

One in 5 Surgical Instruments Are Flawed

According to Brophy, 1 in 5 instruments, or about 20% of all instruments he receives, are rejected due to flaws that place patients' health at risk. He even reports receiving used equipment where blood and dried tissue could pose an infection risk.

These tools are somehow recycled and passed off as brand new — something that simply should not occur. Yet it's happening. Poorly constructed instruments also should not enter the surgical suite, yet they do with frightening frequency. How is all of this possible?

In the U.K., manufacturers and suppliers of surgical instruments must be registered with the Medicines and Healthcare Products Regulatory Agency (MHRA), and there are over 900 manufacturers registered.

In December 2010, following mounting complaints about shoddy quality, the agency issued a warning to all manufacturers saying steps must be implemented to ensure that all instruments are "fit for purpose."

However, the responsibility for ensuring that quality standards are actually met still rests with the manufacturers, not the MHRA or any separate quality control agency. The suppliers are not even required to inspect the products received from the manufacturer before reselling them to a hospital.

In all, there are 215 health trusts and boards in the U.K.,[2] but Barts is the only health trust that actually employs a technologist to inspect all the instruments before they're used in surgery.

Disturbingly, when Brophy sent back rejected instruments to an Asian supplier, he was told that the instruments were sent out to another U.K. hospital that accepted them without issue. "Well, of course they're going to accept them," Brophy says, "because they haven't checked them."

Where Are Surgical Tools Made?

Thoughts of Swiss-made precision come to mind when considering how surgical tools are made, but two-thirds of the world's surgical instruments are actually manufactured in Sialkot, located in the northern Punjab area of Pakistan. Seventy percent of the 900 surgical tool manufacturers registered with the MHRA are based there.

Some of these manufacturers appear to be doing a decent job, including Hilbro, which is one of the largest manufacturers. Each instrument is at least visually inspected with a magnifying glass before being sent out. Others operate under far more questionable circumstances.

Regal Medical Instruments, a small manufacturer in Sialkot that sends their wares to two small-scale suppliers in the U.K., offers a wholly different view of the industry. The facility is so dark you can barely see, and metal dust fills the air. Surgical instruments lie scattered in piles on the floor.

In their quality assurance department, employees visually inspect each instrument before stamping it with the requisite "CE" quality stamp required by the MHRA, but no magnifying glass is used. This means most defects caught by Brophy — who uses a microscope — will never ever be caught.

Then there's "the ramshackle side to the industry," to use Poling's words. In this part of town, workers toil away at their grindstones in tiny dust-filled shacks with open sewers

flowing past their doorways. According to Poling, larger, respectable companies frequently outsource work to these workers in order to meet demand.

In all, there are more than 3,000 of these "outsourcing units" in Sialkot, and these workers make less than $2.50 per day. According to some of the workers, both Hilbro and Regal Medical regularly buy surgical instruments from them.

'Made in Germany' — Not Quite!

Remarkably, the maker's mark on these Pakistani-made tools will often say "Made in Germany." As explained by Poling:

> *"Under EU law, the instruments made in these backstreets can be stamped with another country's name so long as that country helps substantially transform the product. So, as the forged steel they're working with here comes from Germany, the whole thing can be stamped 'Made in Germany,' and German instruments sell for much more than those stamped 'Made in Pakistan.'"*

Making matters worse, British suppliers rarely conduct quality inspections of their Pakistani manufacturers' facilities. Part of the problem is the constant risk of terror attacks in Pakistan. It's a dangerous area, and carrying out inspections in person is risky. Poling also found evidence suggesting the Pakistani surgical tool industry may be using child labor.

The MHRA declined meeting with Poling, but provided her with a statement saying they have "no evidence that non-compliant instruments are being supplied to the NHS." Meanwhile, Brophy inspected the 19 instrument samples collected by Poling during her Pakistani trip, where she visited over 100 different instrument manufacturing facilities. Twelve of the 19 samples failed his inspection.

Poling even unearthed illegal activities during her investigation. While legal loopholes allow for a Pakistani manufacturer to label his goods as "Made in Germany" if the steel used is from Germany, it is illegal to use Pakistani or French steel, for example, and mark it as being German-made.

Undercover footage, in which she poses as a supplier of surgical instruments, shows two U.K. representatives of Regal Medical Instruments offering to sell her tools made with Pakistani steel stamped "Made in Germany," so that she would then be able to resell them at an inflated price. According to the Pakistani representatives, they are already selling mid-priced French steel instruments to suppliers that bear the German mark, per the suppliers' requests.

Nondisposable Equipment Also Carries Contamination Risks

As discussed in my interview with Dr. David Lewis, Ph.D., a retired microbiologist with the Environmental Protection Agency (EPA) last year, nondisposable tools such as flexible **sigmoidoscopes and colonoscopies** are also risky for the patient.

Since they must be reused, these tools require cleaning and sterilization before each use, both inside and out. However, testing reveals that this is virtually impossible, and the disinfection process used by most clinics and hospitals fails to properly clean and sterilize these tools.

As a result, patients take great chances when these tools are used on them, as they spread all manner of infections from one patient to another. There is a solution — create flexible scopes that can be autoclaved (heat-sterilized). But manufacturers have not been pressured to come up with such a design. As noted by Lewis, it really boils down to federal agencies failing to take the contamination issue seriously enough.

If you're having a colonoscopy done, or any other procedure where a flexible endoscope will be used, be sure to ask how it is cleaned, and which cleaning agent is being used.

- If the hospital or clinic uses peracetic acid, your likelihood of contracting an infection from a previous patient is very slim.
- If the answer is glutaraldehyde, or the brand name Cidex (which is what 80% of clinics use), cancel your appointment and go elsewhere.

Asking what they use to clean the scope is a key question that could save your life. It's important that we all start to do this because the FDA simply does not have the incentive to take action on it.

However, once enough people refuse to have these procedures done with glutaraldehyde-sterilized instruments, then clinics and hospitals will change, even if the FDA does nothing. It's also crucial that health care professionals who are reading this start addressing the issue from the inside. You really need to be aware of this issue, and how it's placing patients at risk.

As for flawed surgical tools, there's very little you, as a patient, can do about it. Ideally, hospitals everywhere would hire someone to carefully inspect all surgical tools prior to use. In all, Poling's report reveals there is much room for improvement in this industry, if we are to place patient welfare first.

Sources and References

- [1] Cureus. 2019 Jun;11(6):e4877
- [2] The King's Fund, June 25, 2024