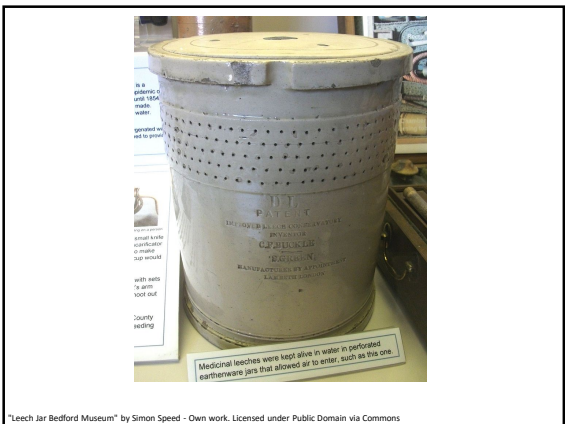


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1. Five questions we ask about care
2. What is evidence?
3. What is good evidence?
4. How to respond to the charge

- Five questions about your healthcare
- Is it safe?
 - Does it work?
 - Is it value for money?
 - Is it acceptable?
 - Is it fair?



"Leech Jar Bedford Museum" by Simon Speed - Own work. Licensed under Public Domain via Commons



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History of Evidence

- Past - Folk medicine
 - Treatment
- Today - Evidence based medicine
 - Disease + treatment
- Future - Personalised medicine
 - Person + disease + treatment

What is evidence in healthcare?

When we use data to answer our questions

- Is it safe?
- Does it work?
- Is it value for money?
- Is it acceptable?
- Is it fair?

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Marbles in a bag

- I have a bag with 60 million marbles in it
- A marble may be red, green or blue
- I want to know how many in the bag are red, green or blue
- How do I do it?

Marbles in a bag – Solution 1

- Pull out a fraction of the marbles and scale-up
 - I pull out six marbles
 - four are red, one is blue, one is green
 - Scaling up by 10m gives ... 40m red, 10m blue, 10m green ... making 60m in total
- Next time I repeat the experiment I pull out 6 blue marbles and get a very different answer!

Marbles in a bag

- So how many do I need to pull out to get an accurate answer?
 - 6
 - 60
 - 600
 - 6000
 - 60000
 - 600000
 - 6000000
- The more marbles I pull out the more reliable the answer, at the cost of time and money

Marbles in a bag – Solution 2

- Pull out every marble and record the colour
 - Exact answer
 - Very time consuming and expensive
 - Impractical to repeat
 - What if the marbles are either small, medium or large
 - What is the marbles are made of wood, glass or metal
 - etc ...
- What would happen if all the red marbles were removed from the bag before we started?
 - Our answer would be very wrong

About health records

- Across the whole of our population we each have a health care record
 - Compare with knowing about each marble in the bag
- Our health records already record detailed information about us
 - Compare with knowing the colour, size, material of the marbles in the bag
- Removing access to records is like removing marbles from the bag before we start counting

Where does evidence come from?

Solution 1

By undertaking highly controlled clinical trials, case-control studies or prospective studies.

PROs – informed consent, high quality data, best evidence

CONs – does not generalise, slow, expensive, narrow scope

Solution 2

By analysing healthcare data collected throughout standard clinical practice

PROs – large numbers, timely, broad, already exists

CONs – not consented, low data quality, potential for confounding

Rofecoxib

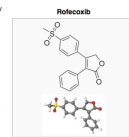
From Wikipedia, the free encyclopedia

Rofecoxib (/roʊˈkiːbɪb/) is a nonsteroidal anti-inflammatory drug (NSAID) that has now been withdrawn over safety concerns. It was marketed by Merck & Co. to treat osteoarthritis, acute pain conditions, and dysmenorrhea. Rofecoxib was approved by the Food and Drug Administration (FDA) on May 20, 1999, and was marketed under the brand names **Vioxx**, **Celebra**, and **Celebrex**.

Rofecoxib gained widespread acceptance among physicians treating patients with arthritis and other conditions causing chronic or acute pain. Worldwide, over 80 million people were prescribed rofecoxib at some time.^[1]

On September 30, 2004, Merck withdrew rofecoxib from the market because of concerns about increased risk of heart attack and stroke associated with long-term, high-dosage use. Merck withdrew the drug after disclosures that it withheld information about rofecoxib's risks from doctors and patients for over five years, resulting in between 88,000 and 140,000 cases of serious heart disease.^[2] Rofecoxib was one of the most widely used drugs ever to be withdrawn from the market. In the year before withdrawal, Merck had sales revenue of US\$2.9 billion from Vioxx.^[3] Merck reserved \$970 million to pay for its Vioxx-related legal expenses through 2007, and have set aside \$4.85bn for legal claims from US citizens.

Rofecoxib was available on prescription in both tablet-form and as an oral suspension. It was available by injection for hospital use.



Rofecoxib, <https://en.wikipedia.org/w/index.php?title=Rofecoxib&oldid=691615884>

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The use of health records

- Must not exploit the population
- Must be open and transparent
- Must be for the public good

1. Should the NHS body be allowed to create these records about you and other patients?

- Yes – the evidence to improve healthcare already exists
- Yes – it is in the public interest
- Yes – it should be done for the entire population to ensure the maximum benefit is gained

2. Given your answer to question 1, who should be allowed to access and extract data from the records created?

- Is it in the public interest?
- Does it benefit the population?
- Does it improve health care by answering:
 - Is it safe?
 - Does it work?
 - Is it value for money?
 - Is it acceptable?
 - Is it fair?