Ethically acceptable limits to blood and plasma safety?
A guide for non-philosophers

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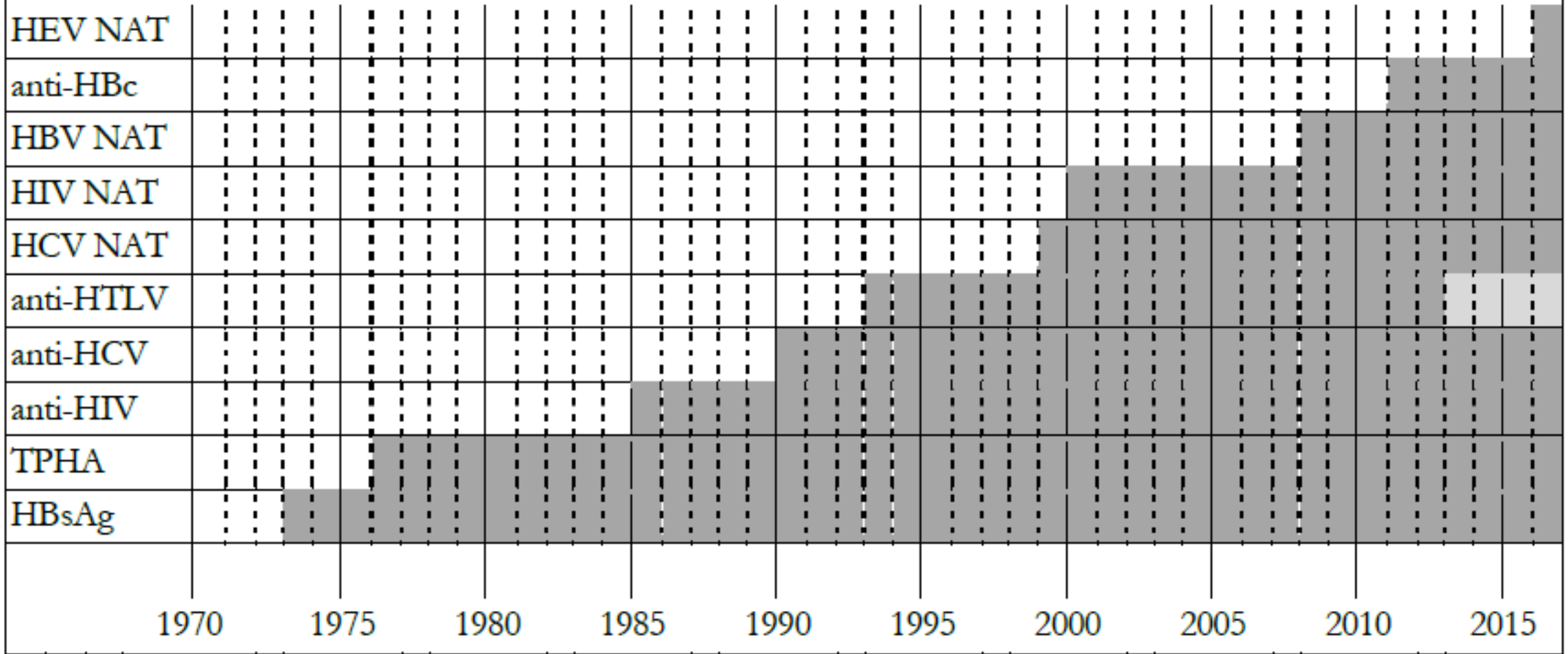
Background: blood safety & cost-effectiveness

Figure 1: Screening tests performed on blood donations for labile blood products, the Netherlands, 1970-2017 (adapted with permission from [6])



Background: blood safety & cost-effectiveness

Some safety measures…

- Address low residual risks
- Involve relatively high costs

… And thus have high incremental cost-effectiveness ratios

- HCV/HIV/HBV-NAT, anti-HTLV I/II: >€1,000,000/QALY (Borkent-Raven et al. 2012)

Research question

(When) is setting limits to blood safety ethically acceptable?

1) Argumentative baseline: utilitarian argument

P1: (~utilitarian): It is ethically right to increase population health

P2: Setting limits to blood safety saves money

P3: Money saved can be used to fund more efficient care

P4: Funding more efficient care leads to increased population health

C: Therefore, it is ethically right to limit blood safety

Accepted as an argumentative baseline:

- It is *prima facie* ethically right to limit blood safety
- Are there compelling counterarguments?

2) Bracketing utilitarian counterarguments

Several premises in utilitarian argument from health economics

- Not my expertise
- Seem robust (cf. proposed CE limits & ICERs in blood safety)

Non-utilitarian arguments barely explored:

- 'We should not set limits to blood safety *even if doing so would enable increasing population health*'
- Possibly overriding considerations, e.g. justice, responsibility, relationship

3) Generating non-utilitarian counterarguments

Literature study

- Ethics of blood safety
- Medical ethics

Qualitative empirical research

- Analysis of policy documents (Kramer et al. 2015)
- Interviews & focus group discussions (Kramer et al. 2019)

4) Evaluating non-utilitarian counterarguments

The “Rule of rescue” argument (Verweij & Kramer 2016)

The “Imposed risk” argument (Verweij & Kramer 2016)

The “Manufacturing standard” argument (Verweij & Kramer 2016)

The precautionary principle (Kramer et al. 2017a & 2017b)

Stopping vs. not starting safety measures (Kramer et al. 2017c)

Example: the “Imposed risk” argument

P1: Not imposing risk may cost more than preventing (‘extrinsic’) risk

P2: Not taking blood safety measures means imposing risks

C: Blood safety measures may cost more than preventing risks

Evaluation:

- P1 accepted for the sake of argument
- Does not taking safety measures mean imposing risks?
- C does not imply that ICERS >€1,000,000/QALY are acceptable

Example: the “manufacturing standard” argument

P1: CE not a legitimate concern for safety of manufactured drugs

P2: Blood products are manufactured drugs

C: CE not a legitimate concern for safety of blood products

Evaluation:

- P2 accepted for the sake of the argument
- P1 depends on opportunity cost: private vs. public

A way forward?

Burden of proof has shifted (?): offer arguments *not* to limit safety

- Insufficient for policy
- Qualitative empirical work (Kramer et al. 2019) generates further arguments

A way forward?

Evaluate further non-utilitarian counterarguments

- E.g. “Double bad luck” argument, “bodily integrity” argument

A way forward?

Evaluate utilitarian argument & counterarguments

- Stakeholders often accept the utilitarian argument in principle…

  “Of course I want to run as little risk as possible. But I am realistic in understanding that it’s not only about me. (. . .) You can’t expect society to spend its money on an individual rather than helping a larger group.” (R07-27 & R07-28)

- ...but often reject its economic premises

  “If I start calculating and cut costs seriously (…) I end up saving around 20 million euros (…) 20 million is nothing in health care.” (P07-28)

Lessons (or discussion points)?

- Clear argumentative strategies can advance blood safety debates
- The utilitarian argument is a good argumentative baseline
- Ethics & qualitative empirical research have a role to play

Thanks for your attention!

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