LUND UNIVERSITY

The Room for Clinical Innovation under Swedish Law

What is the regulatory environment concerning unproven methods in medicine in Sweden?

Lena Wahlberg
Associate Professor of Jurisprudence
Faculty of Law, Lund University
lena.wahlberg@jur.lu.se
www.vbe.lu.se

VBE - Science and Proven Experience

”Unproven methods”

- not established clinical practice
- not approved/recommended by the government
- established/approved but for other purposes
- not published in peer reviewed journals
- still undergoing clinical trials
- not sufficient evidence for safety and efficacy

The Regulatory Framework (in brief)

	Healthcare	Research
Requirement:	**Accord with science and proven experience** *Patient Safety Act (2010:659) chap. 6 sec. 1.* *Patient Act (2014:821) chap. 1 sec. 7.*	**Ethical approval** *Act on ethical vetting (2003:460), sec. 6.*

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What is the room for unproven methods without ethical approval?

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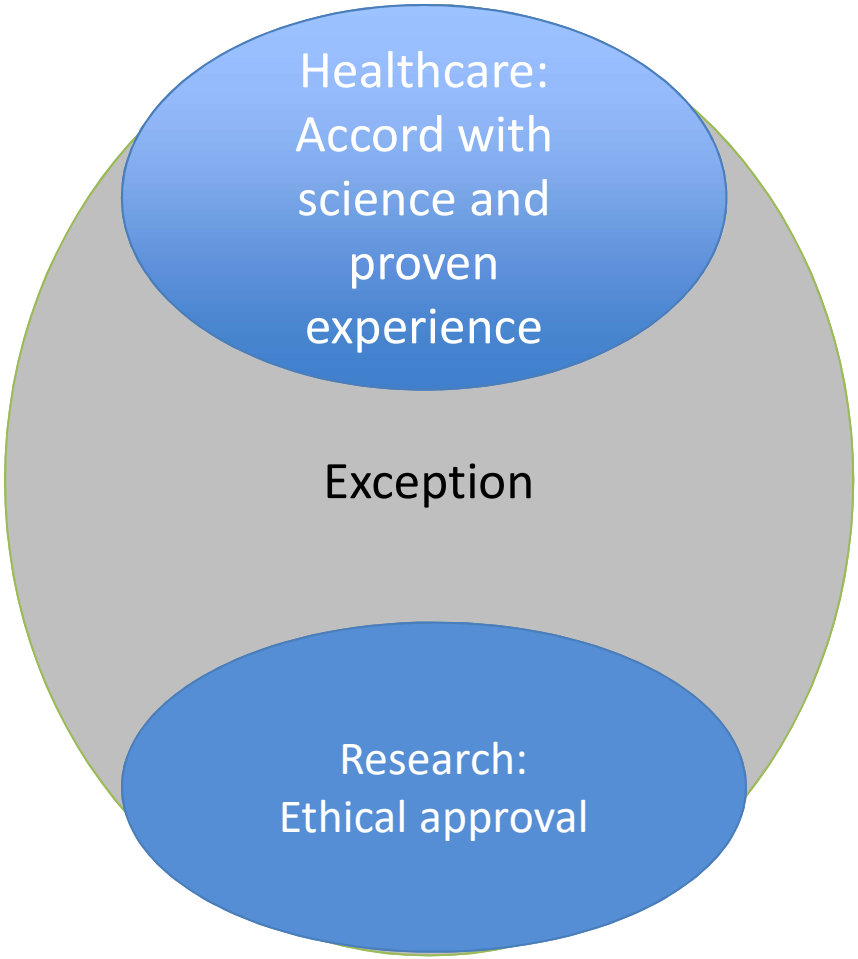
Conceptions of the room for exceptions



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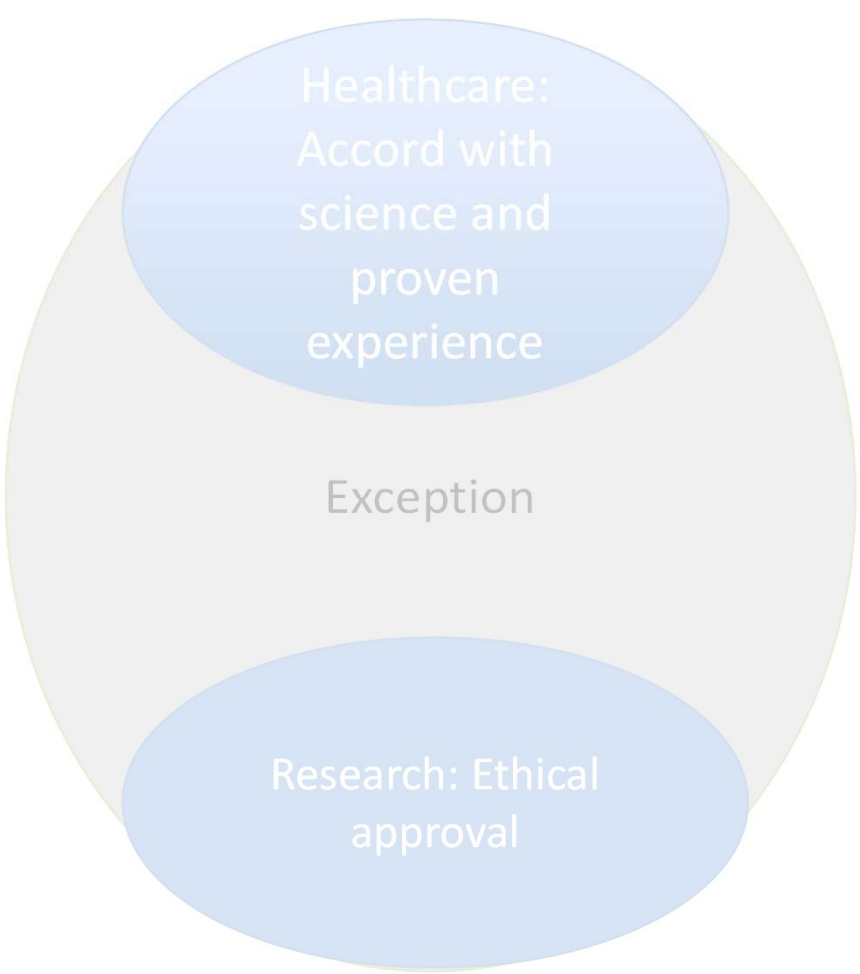

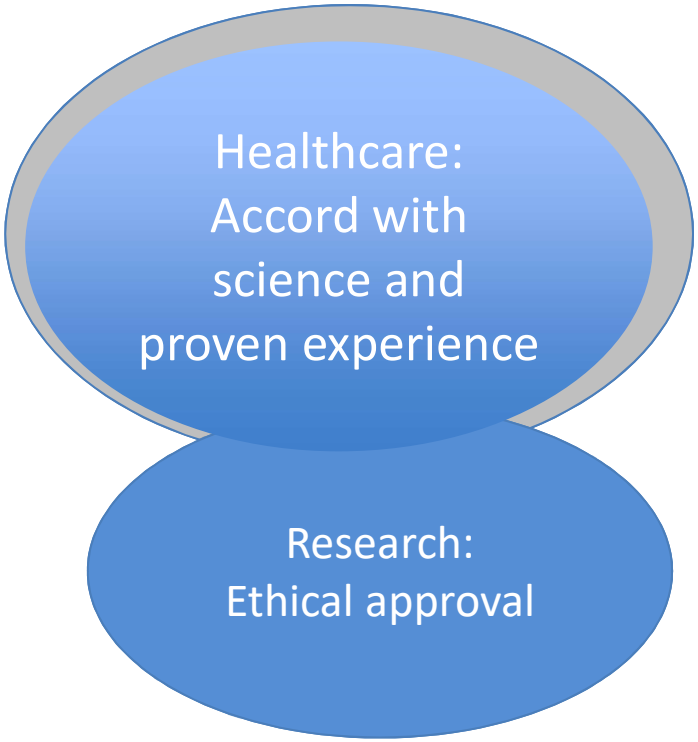

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- approved/recommended by the government?
- published in peer reviewed journals?
- undergone clinical trials?
- sufficient evidence for safety and efficacy?

”The medical doctor must consider both science and proven experience.

When a method is new, proven experience is lacking and scientific evidence suffices for acceptance.

At other times, long clinical experience is the most important evidence for acceptance, whereas theoretical and/or experimental evidence is lacking.”

(The Swedish Board of Health and Welfare, 1976)

Botulinum toxin and sweating

Is the use of botulinumtoxin as a treatment of hyperhydrosis in other body parts than feet, hands and armpits in accordance with science and proven experience?

(Stockholm Administrative Court of Appeal, case 3604-17 and 3605-17.)

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➔The treatment accords with science and proven experience.

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What, then, does the requirement ”accord with science and proven experience” mean?

- There must be sufficient evidence that the treatment is safe and effective *for the patient*.

Wahlberg, L. & Sahlin, N-E., (2017). Om icke vedertagna behandlingsmetoder och kravet på vetenskap och beprövad erfarenhet. Förvaltningsrättslig tidskrift, (1), 2017, 45-66.

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- There must be sufficient evidence that the treatment is safe and effective *for the patient*.
- The *expected benefits* for the patient must outweigh the risk.
- The use of unproven methods can be justified *only* by the expected benefit for the patient – not by the new knowledge they may bring

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- Normally, ”unproven methods” will not be supported by sufficient evidence for safety and effectiveness
- The risk assessment is hard to make and in part subjective
- There is no guarantee that the assessment will survive a subsequent trial.

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- Ethical approval is required when a treatment method is studied scientifically *even* if the method accords with science and proven experience.

- The risk for criminal liability in case of violation of these requirements has so far been very, very low.

Does the legal environment promote or stifle the development of unproven methods/clinical innovation?

Should we change the laws to further promote the development of unproven / new methods, or add further guardings to regulate the process?

Thank you!

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NEWS | All news

7 Sep 2018

Petra Björne, new VBE collaborator!

The VBE program welcomes new collaborator Petra Björne!

23 Aug 2018

Sten Anttila på Almedalsveckan 2018 (in English below)

Under Almedalsveckan anordnade FAMNA - Riskorganisationen för idéburen välfärd - en serie seminarier om ämnen såsom upphandling respektive evidens.

5 Apr 2018

New member of the VBE programme

We welcome Dr. Astrid Kause, from Leeds University, as a new member of the VBE programme!

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VBE in Nature

Barry, Baruch and Nils-Eric critizice the 'moral machine' experiment on both philosophical and psychological grounds.

VBE in Journal of Risk Research

The article "Ruling out risks in medical research" argues for more transparency, when specifying and justifying risk margins, in guidelines for reporting medical research results.