

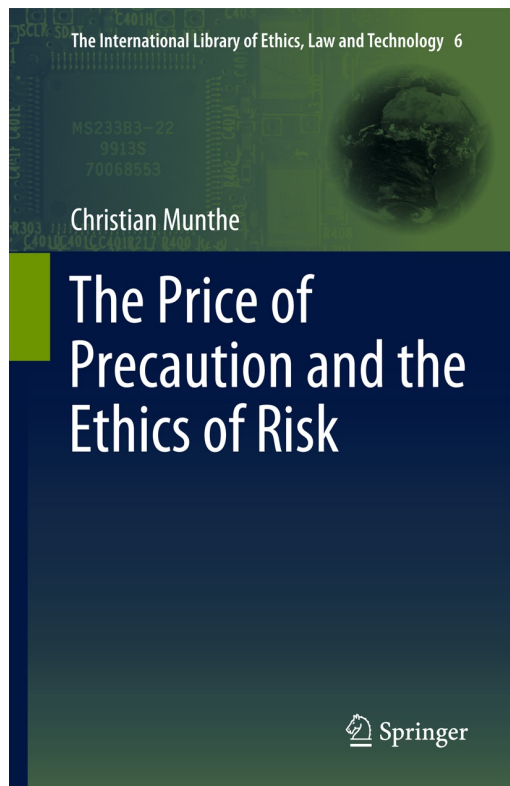


# The Price of Precaution in Frontline Reproductive Medicine



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Standard Article

### Precautionary Principle

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Following the statement in the United Nations' *Rio Declaration* of 1992 that countries should apply a "precautionary approach" in policymaking on environmental and technological issues, the notion of a precautionary principle (PP) has gained ground in worldwide policymaking and regulation, thus catching the interest of ethics scholars. Although seldom explained in much detail, and resulting in quite different policy results in different countries and areas (O'Riordan et al. 2001; Sandin 1999; Trouwborst 2002; Zander 2010), PP is generally understood as a norm urging or permitting policymakers to take preventive action in the face of unknown, uncertain, or probable dangers, motivated by the experience of how seemingly valuable and promising practices may lead to seriously adverse consequences in spite of lack of solid evidence to this effect (Sandin 1999). In ethics debate, this idea has been applied not only to matters regarding the large-scale introduction and use of technology (e.g., regarding energy production, transport and communication, nano- or biotechnology, and so on) (see Biotechnology; Nanotechnology, Ethics of) with possible ensuing impact on the natural environment connecting to the notion of sustainability (see Sustainability), but also, for example, to abortion (see Abortion), medical genetics, embryo experimentation (see Embryo Research), the treatment of animals (see Animal Experimentation), terrorism (see Terrorism), and general research ethics (see Research Ethics) (Munthe 2011). Many of these applications advocate strong conclusions in spite of the fact that PP or its normative justification have not been made very clear. At the same time, PP has been the subject of criticism, much of which boils down to three points: lack of clarity, lack of practicality, and/or ethical implausibility. Curiously, these critical points have often been made in conjunction, in spite of the fact that a clear sense of what PP means seems necessary for backing up the other two objections.



# What's Going On?

- **Human germ-line gene therapy** on the move (mitochondrial replacement)
- **Whole genome sequencing** quickly evolving and moving into prenatal and preimplantation genetic testing
- **Functional genetics and genomics research boosted through** WGS, Big Data, quicker translation into clinical and other practice, etc.
- **Reproductive SCNT**-procedures and **iPS stem cells** for humans "proved in principle"
- **Synthetic biology** moving on backed by huge potential financial prospects
- In the background lingers **ectogenesis** scenarios....
- **People increasingly motivated** to check/control/design "quality" of offspring
- **Social norms** re. reproduction, family & children proven surprisingly plastic and adaptable to technological development
- **Private industry** increasingly stronger and pressing ahead reinforcing the above



# What's at Stake?

- Old demarcation lines becoming increasingly irrelevant: **shift from ending life (in the process) to creating, controlling and designing life** from scratch
- **Prospects of principled / absolutist stances (pro or con) meager**: time to scrap the bioconservatism–transhumanism simplification, and similar unhelpful takes
- The fate of **those (possibly) coming into being** in terms recognized values
- Consequences for **receiving and affected parties** (e.g. parents, siblings)
- **Societal consequences**: long-term re collective mentalities & social order/structure
- **Integrating analysis** of single case, social, institutional and regulative dimensions
- **Accepting comparative evaluations of possible people** (any plausible ethical theory needs to make room for that to some extent post non-identity problem)
- **Accepting limitations of simple maximization norms** (e.g. by acknowledging value of positional goods in the reproductive area post repugnant conclusion)
- Never loose track of **opportunity costs!**

# The Challenge of Ignorance and Uncertainty

- Whatever basis of values and norms is assumed, assessing reproductive medical front-line technologies will pose a huge challenge due to **lack of knowledge**
- The technologies themselves use mechanisms where there is **fragmentary understanding, lack of experience, identified & yet unknown gaps of knowledge**
- Since the mechanisms are reproductive, **even minor consequences may attain dramatic proportions due to the possibility of hereditary effects** (we actually don't know yet, how well PGD works, since transgenerational risks have been discounted)
- Reproduction also **connects to central social practices and (value) systems, where small shifts may have huge negative/positive impact** on people and societies; regulations and institutions taken for granted may disappear very quickly
- It is very **difficult to predict the more long-term consequences on future technological and societal developments** with regard to scenarios of, e.g., children as manufactured commodities.
- At the same time, if the technology works, **there are some obvious more immediate benefits to be had and in the long run also emancipating social scenarios**

# The Price of Precaution...

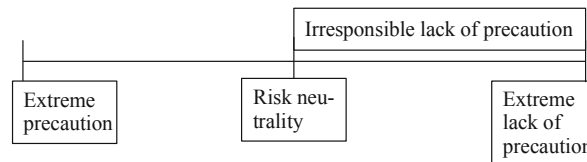
- Assumption: when much is at stake **we have a responsibility to** show that what we do brings an acceptable mix of risks and chances before we do it. Not doing so carries a moral price of **irresponsible lack of precaution**.
- **Precaution has a price as well**, but what determines if such a price paid for a certain degree of precaution is a **proper** one in light of the reason to be responsible?
- **Likelihood and value of possible outcomes** (including indeterminate and qualitative likelihood estimates, such as "possible") of options (including those of "doing nothing", postponing waiting for more info, and so on): opportunity costs
- **Quality of available information**: reason to wait and collect more (but this always has a price in terms of resources needed and benefits abstained from)
- **How are risks and chances to be balanced?** The model of calculated risk-taking where equal risk- or chance-magnitudes have equal ethical importance (e.g. maximizing expected utility based risk analysis) is far from given, neither is the "maximin" and similar solutions
- At the same time, **the price of precaution must be limited to avoid decision paralysis, paradox and obviously implausible results** (sacrificing everything else to avoid one tiny risk) and take into account opportunity costs

# ...and the Ethics of Risk

- Standard ethical theories don't say much informative or useful about these things, although they inform about what is of value and what actions may possibly be out of bounds as means to handling risky decisions responsibly.
- There is a moral/ethical quality (of more or less responsible) that we can ascribe to **risky decisions**, that is not identical to the traditional idea of right/wrong actions or good/bad outcomes.
- Riskiness of decisions means that **what actions and outcomes are produced is indeterminate**, so how should the creation of such an indeterminacy be judged morally in terms of responsibility?
- All of the factors relevant for the price of precaution (likelihoods, outcome values and quality of underlying information of all available options) seem possible to weigh into an assessment, but **how should they be balanced?**
- The **quality of information factor must be relative** to what is at stake and available options: this is "just another option" in the calculus, albeit one connecting to **a specific value parameter**
- **More controversial:** risk neutrality or increased 'weight of evil' approach?

# ...and the Ethics of Risk cont.

- Risk Neutrality:
  - Risks and chances of equal magnitude balance each other out in responsibility terms when options are compared
  - Irresponsible lack of precaution is to decide something where the risks are not thus balanced by chances, more precaution than this is to pay an unreasonably high price of precaution
  - Fits well with standard approaches to risk analysis and within the maximizing expected utility paradigm



- 'Increased weight of evil' approach
  - Morally responsible decision making may require us to pay an even higher price of precaution, e.g. sacrificing more time and money, abstain from more possible benefits in order to certify avoidance of (certain) risks
  - Many possible models that reflect different ethics/value stances
  - My favoured idea is 'indirectly sufficientarianist': If an option secures an "acceptable risk-chance mix" relative to what affected parties stand to lose or gain, risks of other options become more difficult to justify; it is worth paying a higher price of precaution in terms of lost benefits to avoid them.
  - Crucial to identify parties that have less or little to lose by taking risks in order to secure benefits & options meaning that they approach a decent situation from a position of deprivation: **the proper price of precaution is here less than otherwise. Vice versa holds for already comparably well-off parties: *prioritarianism***



# Implications for Reproductive Medicine: clinical aspects

- **General reason to postpone human and, when such are initiated, wider clinical applications** until there is sufficiently well-founded reasons for the claim that such application is "good enough" in terms of what's at stake in terms of risks and chances
- **Reason to align schemes for collecting information** to provide as much benefits and as little harm as reasonably possible
- **Reason to prioritise worst-off** – but who is that besides serious genetic disease victims in light of opportunity costs? How important is it to have **further children**, and how important to have **children in one way rather than another**, or **some children rather than others** (e.g. with or without genetic link to parents)
- Reason for **tight monitoring of clinical application results for a very long time** (at least two generations, patients need to be made aware)
- **Reasons for proceeding slowly, in small steps** and be wary of organisational solutions leading to lack of transparency and difficulty of control, e.g. private business
- Reasons for **limiting or modifying above** in light of evidence in favor of expecting beneficial results, opportunity costs or risks of precautionary measures
- **Preparedness to abstain from or stop** initiated applications in light of evidence
- **The proper price of precaution appears to be rather high....**

# Implications for Reproductive Medicine: societal scenarios

- Need of **regulatory mechanisms** that take into account also these possible effects and the linked need to adapt or create **adequate policy rersponses as facts occur**
- **Specific legislation is an unwise solution** due to the many uncertainties and attached needs for swift adaption and policy change as uncertainties are straightened out.
- **Standard research ethics or general health care ethical regulation insufficient:** too specific or too generic
- **HFEA is a model:** broad scope in assignment of what to look at and critical role of allowing what would otherwise not be banned, while facilitating seamless review from research stage to clinical routine stage as facts occur and including mechanism for public consultation
- **Expect some controversy around how scenarios are to be valued:** what some view as emancipation from the ties of nature, others will see as serious breeches of a prescribed 'natural order' – at the same time attitude plasticity suggests such reactions may be unstable....
- **Positive social scenarios of emancipation do not look very powerful** from a precautionary point of view when balanced against possible long-term uncertainties and risks
- **Negative social scenarios of *dis*emancipation are serious indeed** (commodification of children and reproduction, possibility of tight societal or commercial control of individual choice)
- **Again, the proper price of precaution appears to be rather high...**

# Conclusion

- Frontline reproductive medicine is ridden by much more riskiness, uncertainty and knowledge gaps than what have usually been acknowledged
- Setting the possibility of treating serious genetic disease or (possibly) to overcome infertility to a side, many possible applications appear to have rather moderate clinical benefits, at least when viewed in the context of risks and uncertainties
- Social or long-term attitudinal consequences include both positive and negative scenarios, but the negative ones appear to be much worse
- The positive ones are more controversial, but evaluation is uncertain due to proven plasticity of attitudes in the area of family and procreative culture and policy ideals
- R&D in this area is rather expensive, this money could be used in other areas of health care or wider health policy....
- There appear to be good reasons to accept a rather high price of precaution in this area, including tight, albeit adaptable and flexible, regulation
- Whatever is being done should be followed up for a long time
- Put it all together: will the costs required for responsible handling ever be justified in light of needs in other areas?