Regulating Germline Genome Editing: Some Key Ideas in the Debate

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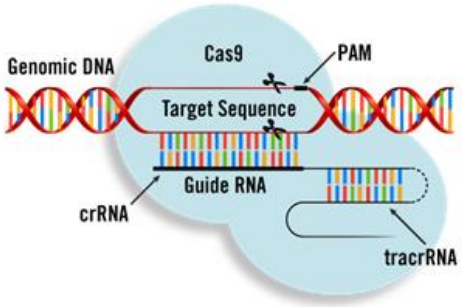
1. Germline genome editing & the first International Summit

Human genome editing (HGE)



- Two main types:
  - Somatic
  - Germline (GGE)
- Potential applications:
  - Treatment of diseases
  - Prevention
  - Enhancement of normal traits
- GGE & enhancement applications are especially controversial

The first International Summit on Human Gene Editing (2015)

- Statement of the Organizing Committee: before any clinical use of GGE becomes acceptable, 2 conditions must be met:
  1. Adequate evidence of safety & efficacy
  2. There is "broad societal consensus" about the appropriateness of the proposed application

- 2nd requirement no longer present e.g. in 2017 report on HGE by US Academies, or in statement from 2nd International Summit in Hong Kong

- This omission has elicited criticism: e.g. Baylis 2017, Hasson & Darnovsky, 2018; Hurlbut, 2019

The recent call for a moratorium

Adopt a moratorium on heritable genome editing

Eric Lander, **Françoise Baylis**, **Feng Zhang**, **Emmanuelle Charpentier**, **Paul Berg** and specialists from seven countries call for an international governance framework.

- Cf. Lander et al., 2019 (comment in *Nature*)
  - Although moratorium in scientific community already proposed before (Lanphier et al., 2015)
- Propose that nations voluntarily commit not to allow any clinical use of GGE for a fixed period (e.g. 5 years)
- After that, they could choose to proceed – but only after certain conditions are met, including consensus requirement

2. The requirement of "broad societal consensus"

What does "broad societal consensus" involve?

- Somewhat ambiguous if left unspecified – could be equated with:
  - Merely a desirable ideal to strive for
  - A principle of *self-regulation* for scientists
  - A call for democratic governance of GGE that respects views of majority of citizens
- As spelt out by proponents of a moratorium:
  - = principle to guide public policy on GGE
  - Taken to represent democratic governance: all citizens, not just scientists, should have a say
  - Yet supposed to be *distinct* from majority rule (Baylis, 2016; Lander et al., 2019)

"Broad societal consensus" as a guide to public policy

- Most clearly spelt out by Françoise Baylis (2016, 2017a, 2017b)
  - Doesn't require unanimity, but can't either be equated with majority rule, "which clearly would be ethically suspect in this context" (2016)
  - More stringent demand: roughly, absence of sustained objection from any minority group
  - Cf. "the Navaho way of discussing an issue 'until there is unanimity of opinion or until the opposition feels it is no longer worthwhile to urge its point of view'" (2017a)

3. Some problems with the consensus requirement

Seems at odds with democratic governance

- Majority rule (among citizens or their representatives) = key decision-making procedure in democratic societies
- Not so clear why it would be "ethically suspect" to appeal to it in this context
- Possible reply: constitutional democracies limit majoritarianism in certain circumstances
  - In particular, when a majority decision would violate the fundamental rights of a minority
- Question: do such circumstances obtain in the case of GGE?

Why might majoritarian governance of GGE be problematic?

- Whose fundamental rights might a majoritarian decision to proceed with (reasonably safe) clinical applications of GGE foreseeably violate?
  - *"Edited" future people*: might apply to *some* uses of GGE, but not *all* (even non-therapeutic)
  - *The disabled*: no more than accepted practices like selective abortion, i.e. questionable
  - *The economically disadvantaged:* some non-therapeutic applications might, but only assuming pessimism about widening access
  - *Parents who don't want to use GGE:* if GGE safe, why would pressure to use it violate their rights any more than pressure to educate, vaccinate, use modern technology, etc.?

4. Is a moratorium desirable?

The rights and wrongs of a global moratorium

- Does not distinguish between therapeutic and non-therapeutic applications
- *For therapeutic applications*:
  - For sake of ensuring safety: could reinforce protections where GGE not currently banned (Schaefer, 2019)
  - Yet might lack flexibility, esp. if lengthy & renewed
  - Is more time really needed for further public debate?
- *For non-therapeutic applications*:
  - Stronger grounds for moratorium to secure time for debate
  - Yet conversation should not just focus on GGE, but more broadly on ethics of non-therapeutic genetic selection

"Designer babies" are already here

Taken from; https://www.fertility-docs.com/programs-and-services/pgd-screening/choose-your-babys-eye-color.php

5. Conclusions

Conclusions

- Nothing wrong with voluntary initiatives to foster broad societal consensus about GGE
- Yet as principle of public policy on GGE, consensus requirement seems at odds w/ democratic governance
- Unless GGE can be shown to foreseeably violate fundamental rights, consensus requirement arbitrarily imposes a naysayer's veto on clinical uses of GGE
- Moratorium may have merit given need to ensure safety
- Though more flexible measures might be preferable, esp. in long run

Thank you!

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