

Regulation of Human Germline Genome Editing After the He Jian- kui Incident: Some Takeaways from the Two International Summits

Alexandre Erler

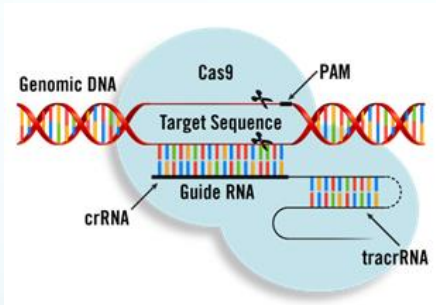
The Chinese University of Hong Kong
Workshop on “Ethics & Regulation
of Emerging Technologies”
CUHK, 12/06/2019

Plan

1. The two International Summits and the associated debates
2. Some relevant issues requiring further discussion

1. The two International Summits & the associated debates

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 HGE (Washington DC, 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
- Societal consensus requirement:
 - = 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)



The 2nd International Summit on HGE (Hong Kong, 2019)



The 2nd International Summit on HGE (Hong Kong, 2019)

- Statement by the Organizing Committee:
 - Confirms that “proceeding with any clinical use of germline editing remains irresponsible at this time”
 - Yet also presents “translational pathway” towards such uses
- Societal consensus requirement no longer present
- This omission has elicited criticism: e.g. Baylis 2017, Hasson & Darnovsky, 2018; Hurlbut, 2019
- Instead, presidents of US & Chinese Academies emphasized need for broad *scientific* consensus on “responsible pursuit” of GGE (Dzau & al., 2018)

The recent call for a moratorium

- Cf. Lander et al., 2019 (comment in *Nature*)
 - 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 societal consensus requirement
- More recently: open letter to US Secretary of Health & Human Services calling for global *binding* moratorium
 - Signed by 62 doctors, scientists, & bioethicists

2. Some relevant issues requiring further discussion

Scientific consensus on safety: beyond democratic oversight?

- Role of scientific experts in informing assessment of safety & efficacy of GGE is beyond dispute
- Yet what counts as “safe enough” partly depends on value judgments
- E.g. is it enough if risk-benefit ratio (RBR) of GGE is better than letting nature take its course? If not, why?
 - “Had sexual reproduction been invented by scientists rather than resulting from our evolved biology, it would never have been licensed - far too dangerous!” (Harris, 2015)

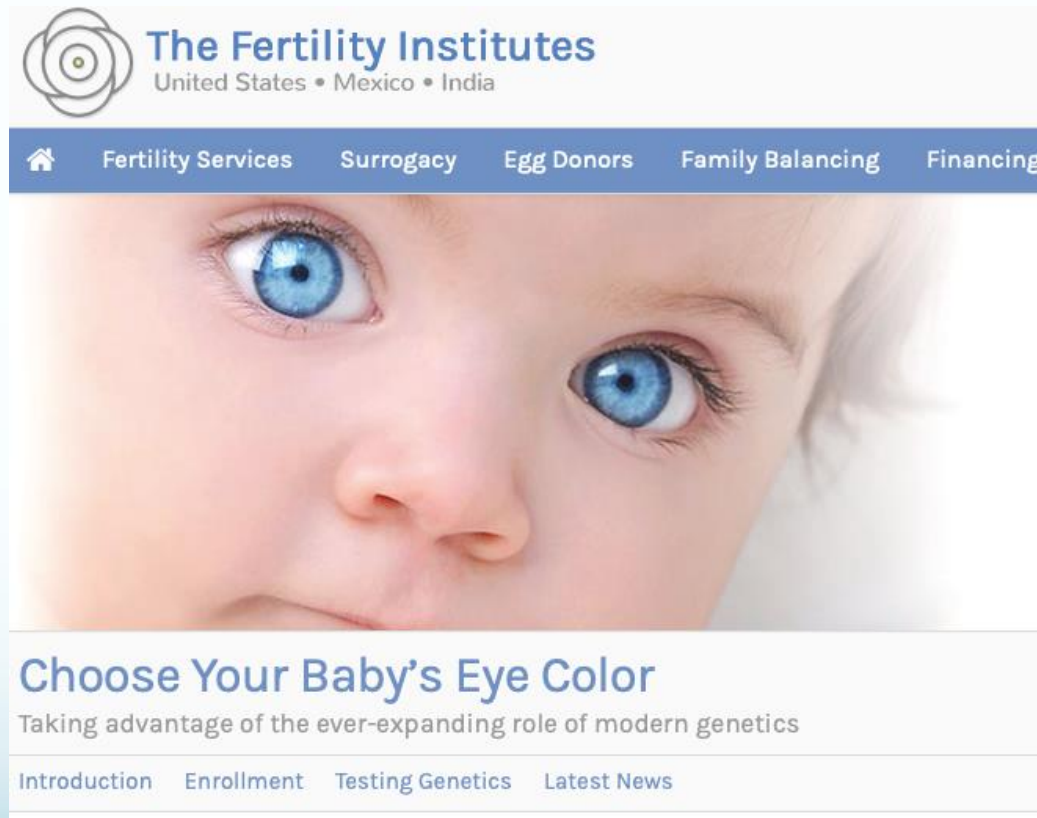
Broad societal consensus & democratic governance

- 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
- But questionable whether such circumstances do obtain in the case of GGE

The rights and wrongs of a global moratorium

- Is it enforceable at all?
- 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
- *For non-therapeutic applications:*
 - Securing adequate RBR will no doubt require more time
 - Yet conversation should not just focus on GGE, but more broadly on ethics of non-therapeutic genetic selection

“Designer babies” are already here



The Fertility Institutes
United States • Mexico • India

Home Fertility Services Surrogacy Egg Donors Family Balancing Financing

Choose Your Baby's Eye Color
Taking advantage of the ever-expanding role of modern genetics

Introduction Enrollment Testing Genetics Latest News

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

Thank you!

erleralexandre@cuhk.edu.hk