Ethics of clinical innovation. Now with video by J. Sugarman

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Abstract:

In this presentation, Dr. Mastroleo defends the view that clinical innovation should be understood, following Levine, as non-validated medical practice. Moreover, he argues that if this is the correct interpretation of clinical innovation this implies that the ethics of clinical innovation are different from (some) clinical research and validated medical practice. PICTURE: Anna Boksa, "Damian". Addendum April 13, 2019: As one of the world experts in ethics of non-validated practice I think you would enjoy watching this discussion at the NIH: Sugarman, J. (2017). NIH VideoCast - Ethics Rounds: Offering Patients Innovative Therapy: When Is It a Good Idea? Retrieved May 24, 2018, from https://videocast.nih.gov/summary.asp?Live=21779&bhcp=1

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Ethics of clinical innovation

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CONICET-FLACSO-UBA

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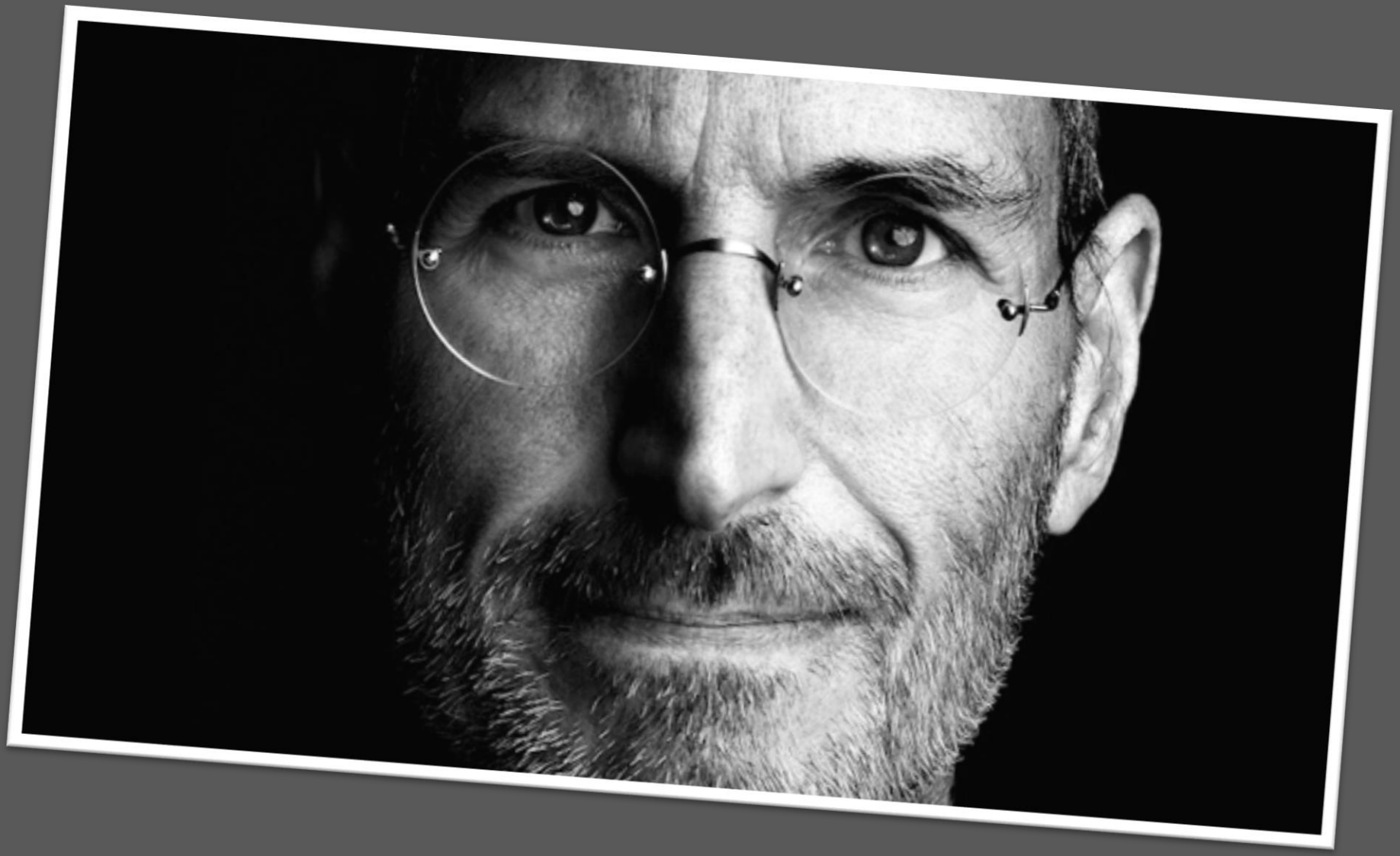
Work in progress, warning!

- This presentation is based on the paper "Clinical Innovation for individuals with no reasonable alternatives" by Holzer, F. & Mastroleo, I.

- *It has not been submitted to journal peer review yet*


What is clinical innovation?
What do you think when you hear “innovation”?
(1´)



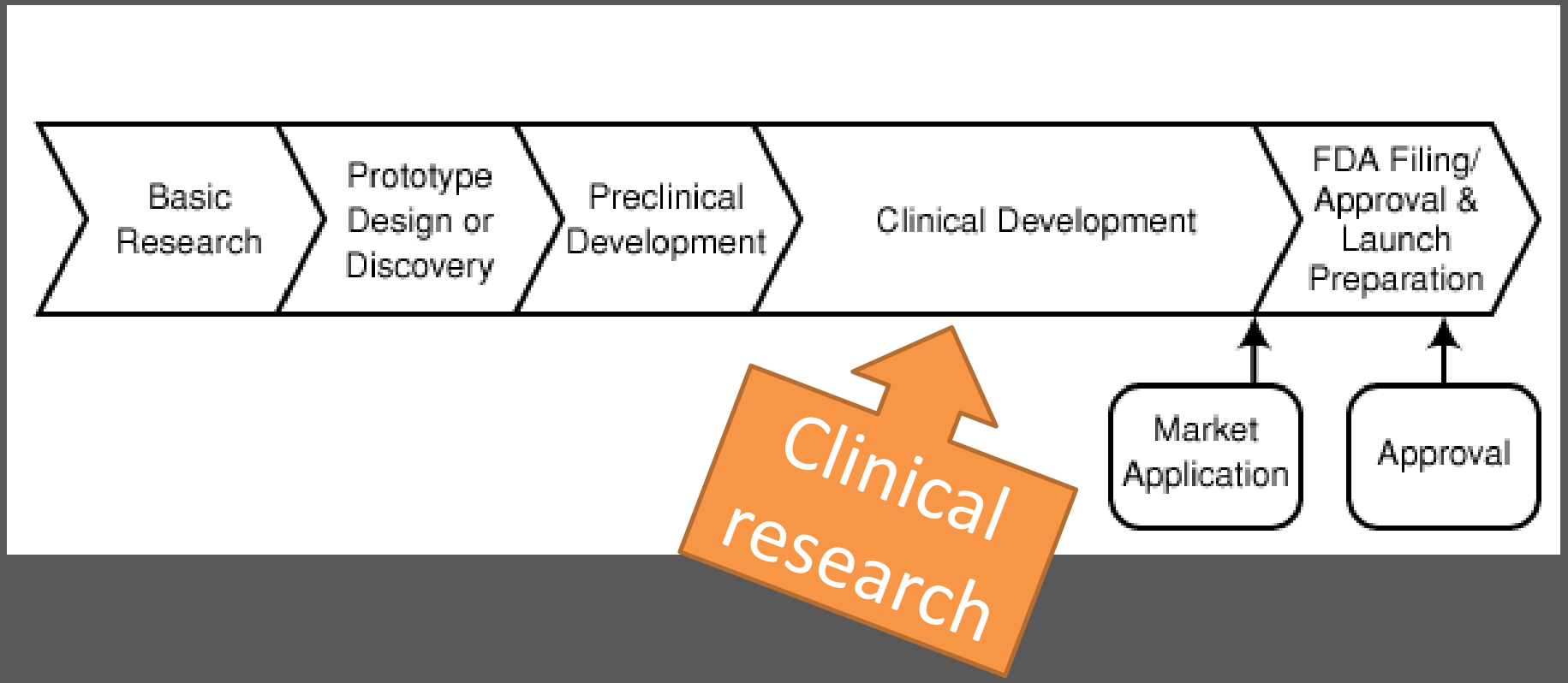
General definition fo innovation: “novelty”, “change”, “improvement”, etc. (Beregheh, Rowley and Sambrook 2009)

- General definition of innovation is too broad and misleading to define clinical innovation
  - Too broad. General definition of innovation includes clinical research
  - Misleading. Not every novelty is necessary an improvement.

(Holzer 2015, editado)

Problem 1. Too broad

- Linear model of “pharmaceutical innovation”



Vasen (2016), edited

Problem 1. Too broad

- Clinical innovation "[…] do[es] not follow the linear model of basic research, to translation, to clinical research, to application."
- Clinical innovation "[…] come[s] from thinking backwards from the patient's circumstances, and forward from deep knowledge of how the body functions, to challenge the limits of current mechanisms for […]" for diagnosis, prevention and treatment.

(Taylor 2011: 286, edited)

Problem 2. Misleading

- Innovation is not necessarily improvement

Galaxy Note 7

Thalidomide (Contergan)


So… what is clinical innovation?

Clinical innovation is non-validated medical practice (Levine 2008)

- It is not research, it is not validated medical practice
  - It is not research because its primary aim is patients wellbeing
  - It is not validated medical practice because of the insufficient evidence
- “Practice” includes new therapeutical, preventive, diagnostic interventions or a combination of them


Why do we need ethics of clinical innovation?

A Cautionary Tale of ‘Stem Cell Tourism’

Carlos Moreno para The New York Times

Jim Gass has undergone stem cell therapy at clinics in Mexico, China, and Argentina to try to recover from a stroke. But doctors found a huge mass with someone else’s cells growing aggressively in his lower spine.

Kolata, G. (2016, junio 22). A Cautionary Tale of ‘Stem Cell Tourism’. *The New York Times*. Recuperado a partir de http://www.nytimes.com/2016/06/23/health/a-cautionary-tale-of-stem-cell-tourism.html

Jim Gass has undergone stem cell therapy at clinics in Mexico, China, and Argentina to try to recover from a stroke. But doctors found a huge mass with someone else's cells growing aggressively in his lower spine.

Carlos Moreno para The New York Times

“I visited the clinic of Dr. [xxx] [in Argentina]. They used my own stem cells so there is no possibility the tumor came from them as the tumor was comprised of cells other than my own.”

Jim Gass, personal communication 30-06-2016, edited


OK. What do we do now?

Use guidelines and regulations of clinical innovation

- We have regulations and ethical guidelines to distinguish appropriate clinical innovation from misuse of non validated practice:
  - "unproven interventions in clinical practice" (WMA 2013, para. 37)
  - "medical innovation" (ISSCR 2016)
  - "expanded access (compassionate use)" (FDA 2016)
  - "use for unregistered interventions" (WHO 2014)

An ethical framework for clinical innovation?

1. Priority of patient well-being
2. Contribution to generalizable knowledge
3. Exhausting circumstances and limited number of patients
4. Scientific validity
5. Independent review
6. Informed consent
7. Publication of results

(Mastroleo, Holzer, Mertelsmann 2016)

Conclusions

- Clinical innovation and clinical research are different but necessary
- More conceptual research on ethics and regulations of clinical innovation will minimize curving access to life saving interventions
- Education in ethics of clinical innovation will minimize the misuse of innovation pathway

Vielen Dank!

Milstein and Kohler (1984)

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Acknowledgments

APENDIX