

Leading Group Task Force on Innovative Financing on Health

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Joris Vandeputte

Background

- Classical Funding Poverty related diseases: **Grants** by Government Money, EU, Gates, others.....
- Financial crisis put extreme pressure on all sources
- Basic research, discovery – access to existing tools: relatively OK
- Translational research: urgent need to think differently
- Translational research= translation of knowledge into globally accessible products
- TBVI has several promising vaccine candidates in its portfolio

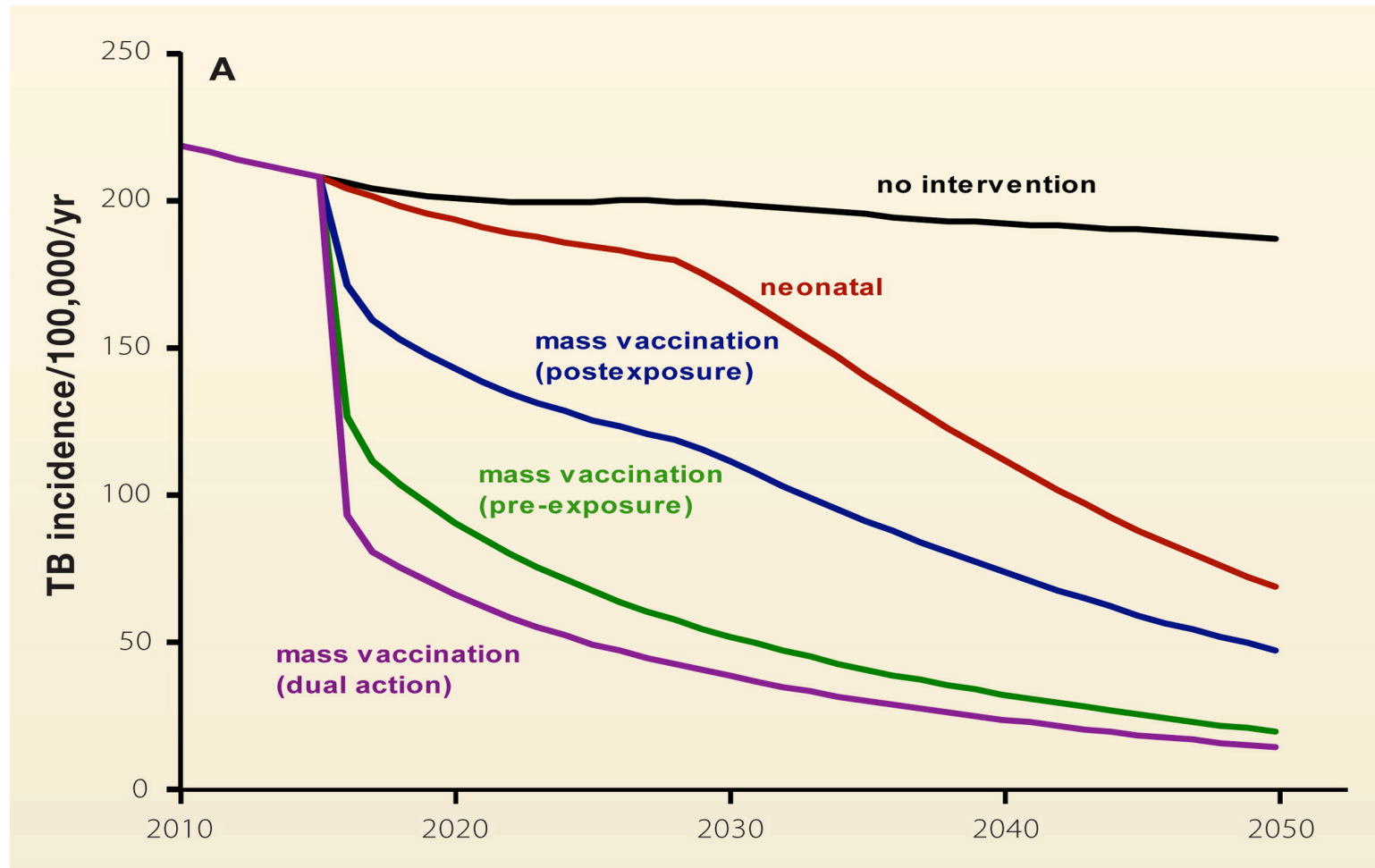
The case of TB vaccines: TBVI

- **Existing BCG:** 90 years old, safety **insufficient**, not protective enough for pulmonary TB
- **Hence:**
 - almost 2 million deaths, thousands in the EU, + 10 million new cases yearly
 - one third of world population latent carrier= source TB
 - huge economic cost=0,52 % GNI yearly
 - worrying also in Europe: MDR, XDR
 - cost: treatment alone: near 10 Bn worldwide, 2 Bn € Europe alone yearly



Potential impact of vaccination on TB control

(D. Young & C. Dye, Cell, 124,2006)



TBVI: portfolio and opportunities

- Consortium of 40 European Research Institutes
- Objective: develop **globally accessible vaccines** for TB: active and safe
- portfolio 39 vaccine candidates, *19 well advanced*
- Candidates showed advantages over BCG
- Portfolio allows **selection** of best candidates
- **If funded now: can select the best candidates to bring at least two vaccines to the market by 2020, if not: risk of total loss!**



Particularities of translational research innovative vaccines for TB

- **Long term:** 10 years at least
- Markets in LDC's and emerging countries
- Market perception **was** bad
- Existing funding systems aim either basic research or access to existing products/services
- **Expensive:** Pre-phase I 2 million €, Phase I 2,5 million €, Phase II: 35 Million €, Phase III: 160 million €



What can be financed, what not?

Discovery/ Preclinical	Pre-phase I	Phase I	Phase IIa	Phase IIb	Phase III
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Classical instrum (grants)



Critical financing gap: class
instr do not work

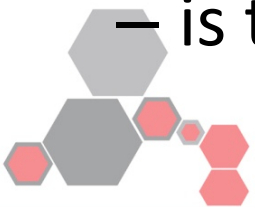


Cl. instruments could
come in if crit. fin. gap
filled and proved
success



Questions frequently posed

- Decision makers:
 - Where to find money in Financial crisis?
 - Which problem will this solve in my backyard?
 - Can you propose a solution, business case?
- New business model:
 - where will financial effort lead to?
 - is there a market?
 - is there a return on investment?



Basics of TBVI's finance plan 1

- Change paradigm: investment case
- Compromise state budget control and 3% GNI innovation commitment (EU 2020)
- Societal advantages for society
- TB a major threat for mankind, MDR, XDR, Poverty reduction
- Vaccines a cost/benefit human success story
- **Hook in the EU: Innovation EU 2020** Flagship initiative, EU 2020 programme Barroso/ TB elimination by 2050



Basics of TBVI's finance plan 2

- Finance pre-clinical and clinical development (Pre-phase I, phase I, phase II, phase III) to fill the critical financing gap of 560 Mio €, 10 years
- Bring two vaccines to market
- System: raise the money needed at the EIB, under state guarantee, and pay back **only** with exits (selling of projects) or royalties on sales



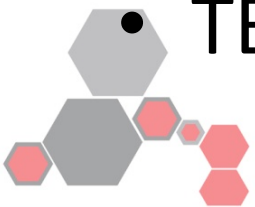
Real interest decision makers for *global win win approach* LDC, emergent, developed

THE INNOVATIVE FUNDING PLAN IN SHORT



How will it work?

- Step wise approach: proposals need approval for funding
- 11 are already ready for funding, 8 more to come
- Contract between TBVI and partners, with conditions such as global access and **exit or royalty** to pay to TBVI
- TBVI pays back the loan



How will it work: Decision Making

- **Representation** of Guaranteeing parties and EIB and other stakeholders
- **Independent decision** process: persons independent from the projects
- **Transparency**
- Selection on **technically and scientifically** fixed gating criteria and **affordability** for LDC's



Do funded partners take any risk?

- Technically: their normal risk
- **Financially: no.**
- **Successful partners (= vaccine candidate is on the market) only pay back AFTER they cashed:**
 - when they made added value by exit
 - or by royalties



This plan offers

- **Stability** of funding over 10 years
- **Quick start of development and translation** of best candidates into globally accessible vaccines= portfolio effect
- **Simplification** of funding
- **Responsibility** to guaranteeing parties to justify choices
- **Minimal or no risk** for governments since no cash and repay foreseen
- **Value creation** of done investment (est. 250 M €)

INVESTMENT MEETS SOCIETAL CHALLENGES

- SAVE 2 million lives the earliest possible
- 0,52 % growth if TB eliminated
- Avoid human dramas for millions
- Finish ticking of a sanitary Time Bomb
- Virtuous circle translating knowledge into innovation generating new knowledge & innovation
- Added value for North and South through strengthened North/South South/North, South/South collaborations



CONCLUSION

- Make a **business case** of translation research projects
- **Two fat birds with one stone:** poverty reduction through TB elimination and added value through translation of knowledge into innovative vaccines

