THE ENVIRONMENT OF CLINICAL TRIALS IN EGYPT

and recommendations given to the Egyptian government

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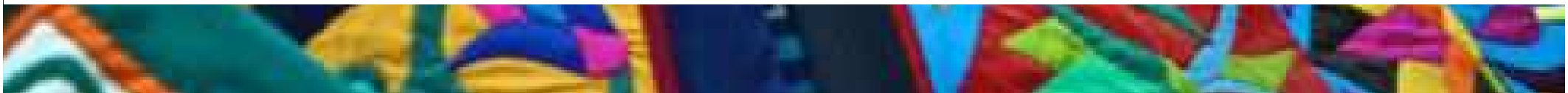


CURRENT FUNCTIONING OF THE EGYPTIAN HEALTHCARE SECTOR

FINANCING OF HEALTHCARE IN EGYPT

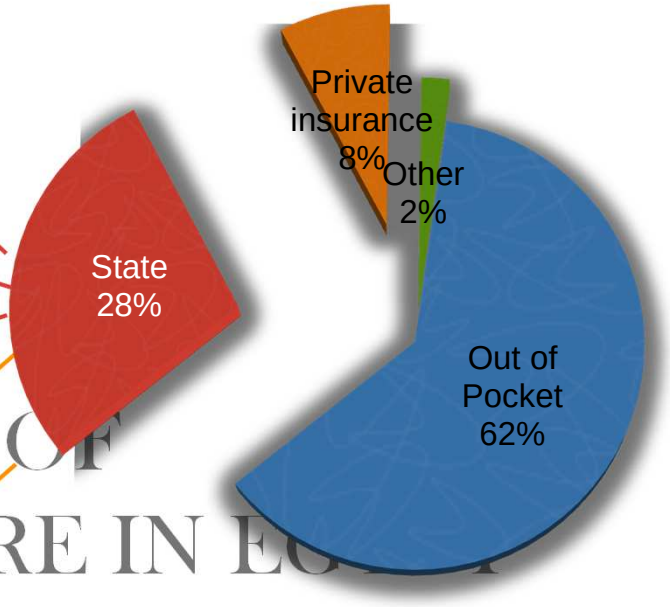
University Hospitals

Military hospitals

Police hospitals

Ministry of health hospitals

Curative Care Organization



Data Source: Egypt, National Health Accounts
2007/2008

COVERAGE OUTCOMES

- 54% are officially claimed to have a health insurance coverage.
- Only 8% of those actually utilise the health insurance services.
- The general satisfaction from the public sector is low.
- The private sector and out-of-pocket payments are rising.
- This has a severe significance in the equity and accessibility components of the Right to Health.

SOCIAL JUSTICE GAP IN HEALTH

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- Egypt is ranked 112 over 173 country in the 2012 human development Index
- 23% of the population is under the poverty line with 7% living in extreme poverty.
- The past decade has been witnessing a strong wave of political and economic instabilities, aggravating the economic and social gap of the population.
- Economically disadvantaged people, specially those living in rural communities, suffer from accessibility issues when it comes to receiving the medical services they need.
- Infant Mortality Rates in rural communities is 2.5% higher than in urban areas (DHS 2008).
- Poor people spend relatively more on health than the rich.
- The Public to Private expenditures ratio on healthcare is lower in the poorest governorates. In other words: The state spends relatively less on healthcare in poor areas.

WHY IS EGYPT A FERTILE GROUND FOR INDUSTRY-SPONSORED CLINICAL TRIALS?

WHY EGYPT?

- Attractive research infrastructure.
- Fast-growing, treatment-naive population.
- Lower costs, cheap human resources.
- Double burden of disease in a growing population.
  - 150,000 new HCV case every year.
  - Prevalence of hypertension and its complications has reached 39.7%
  - Prevalence of diabetes and its complication has reached 17%
  - 100,000 new cancer case each year
- Poor state of legislations protecting the rights of patients in general and clinical trial participants specifically.
- Lack of public transparency, social accountability and civil society access to information.
- Social injustice, economic struggles and poor accessibility and affordability of treatment.

MAIN FINDINGS

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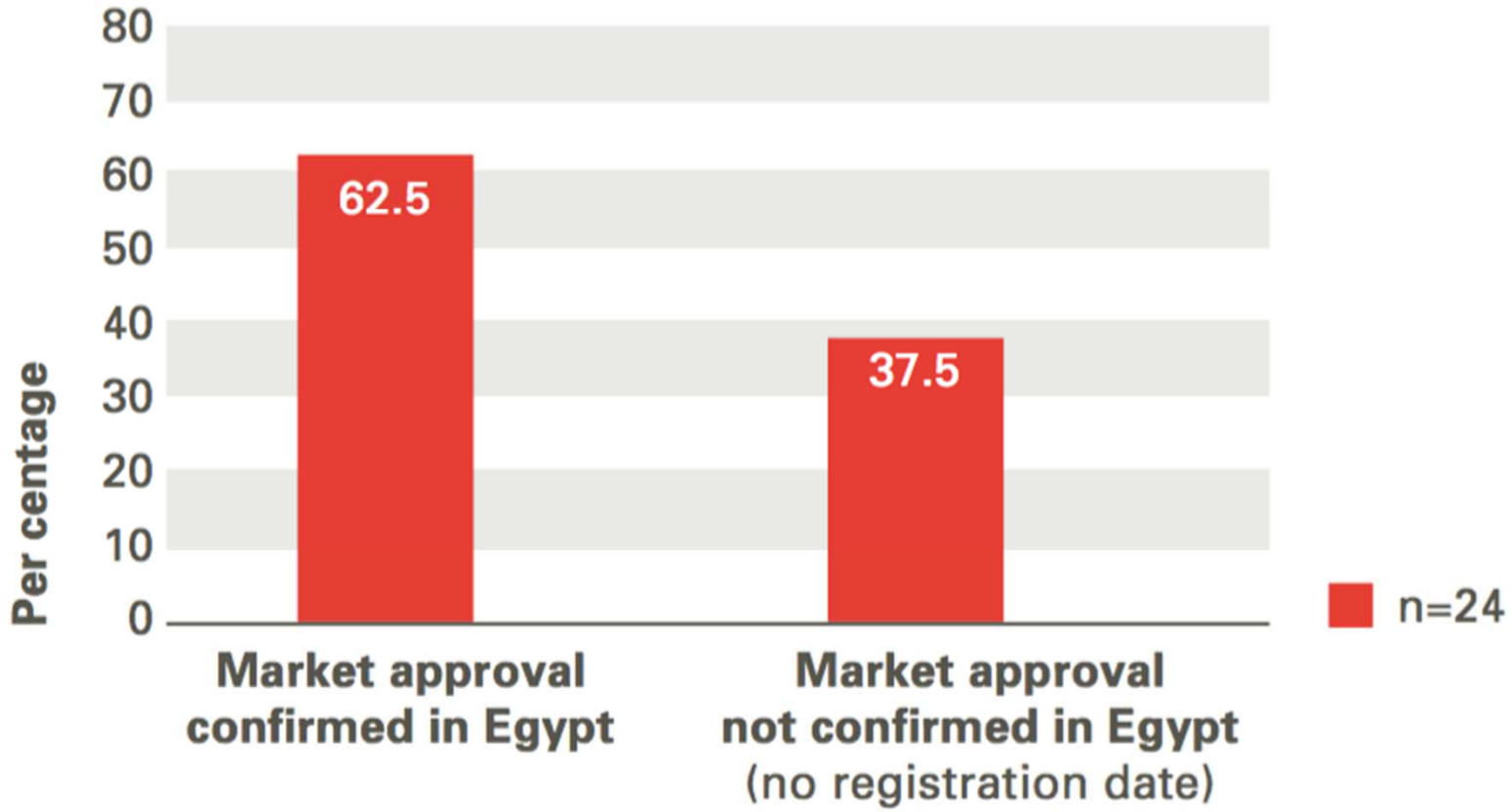
- Vast majority of clinical trials are end-stage, licensed in high income countries.
- Yet, 16% of current trials are Phase I and II ??
- Concerns related to availability of information and legislative framework.
- Participants often take part in trials because of lack of the financial means to undergo treatment using proven modalities.
- Concerns related to Post-Trial Access and Affordability of treatment, a monthly treatment with some of the medicines surveyed costs more than 20 times the official monthly minimum wage of the public sector
- Only a small amount of medicines tested in Egypt were approved for marketing in country.
- Concerns about transparency and conformity to international obligations.

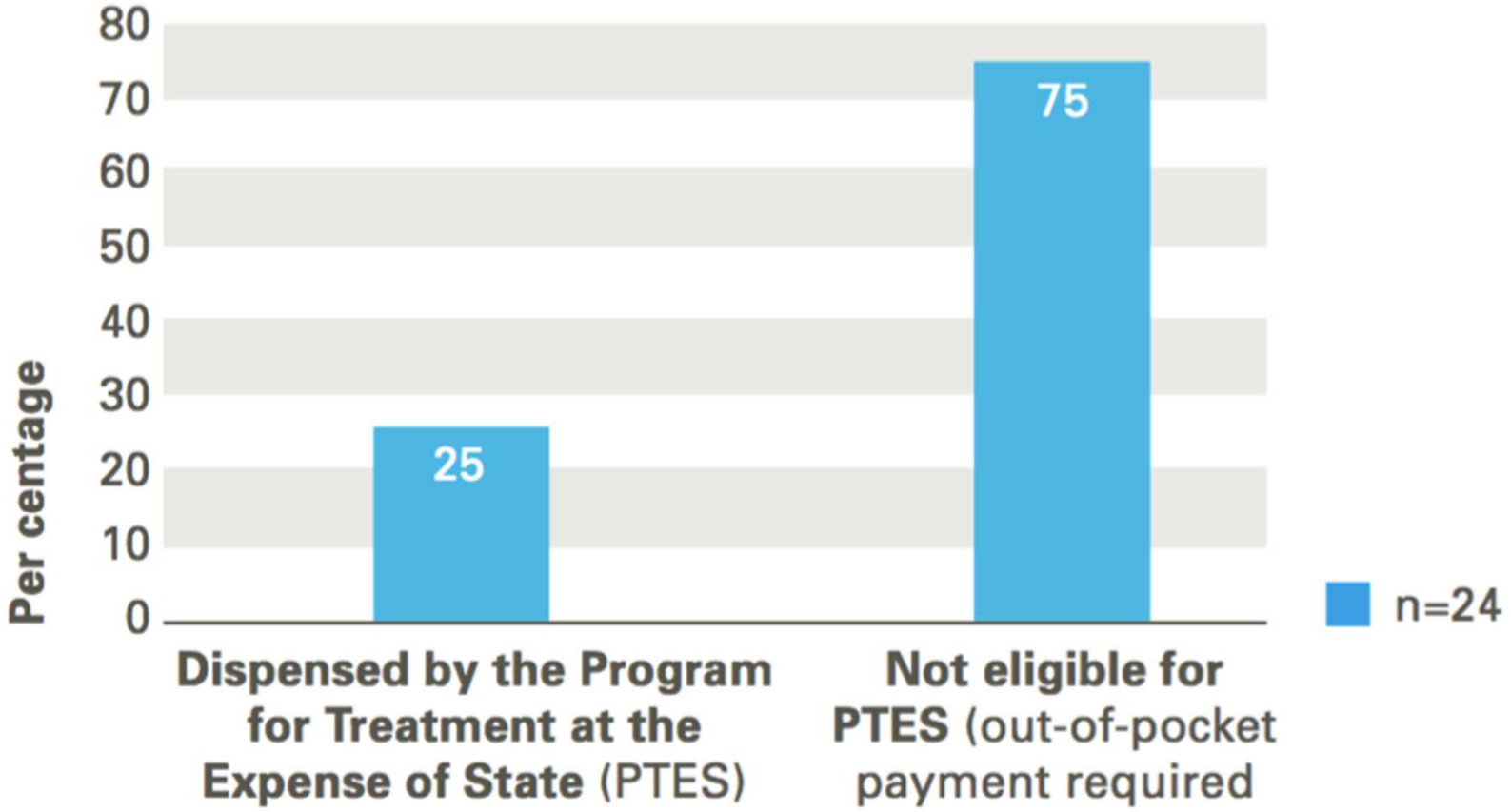
MAIN FINDINGS

FIGURE 4: **proportion of marketing approvals**



MAIN FINDINGS

FIGURE 5: **Proportion of medicines tested in Egypt eligible for a state-subsidised treatment**



MAIN RECOMMENDATIONS FOR EGYPTIAN AUTHORITIES

RECOMMENDATIONS FOR EGYPTIAN AUTHORITIES

1. A single, robust legislative framework with a functional independent control system that:
    a. Clearly establishes conditions of trials
    b. Regulates funding, monitoring & promote transparency
    c. Address legislative gap concerning Phase 1 and 2 trials.
    d. Take the Declaration of Helsinki CIOMS guidelines and reference.
    e. Tackle selection and composition of IRBs.
2. Create an online, up-to-date public registry of trials.
3. Maintain vigilance over conducting Phase 1and 2 trials.
4. Include education about research ethics in curricula.
5. Ensure access to information to the public.
6. Legislation that protects patients' rights.

RECOMMENDATIONS FOR EGYPTIAN AUTHORITIES

The government should refrain from approaching clinical research as a mere vehicle for the delivery of unproven treatments to participants with limited financial resources.

This change in mindset is key where participants are particularly vulnerable.

This creates an increased likelihood of patients being wronged or of incurring additional harm.

THANK YOU

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