Recruitment barriers associated to prophylactic vaccine trials in Belgium

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Disclosure

– Employee of GSK Biologicals, Belgium
– Secondment at the Centre of Excellence for Vaccines (hosted at the FAMHP), October 2016 to March 2017
– GSK had no influence over this project and had no privileged insight to project results
Introduction to clinical trial recruitment

Proportion of clinical trials reaching their recruitment target

Proportion of clinical trials completing recruitment stage on time

Swan et al., 2009, Warwick Business School
Why specifically assess recruitment barriers for PVTs?

<table>
<thead>
<tr>
<th>Therapeutic products</th>
<th>Prophylactic vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aim to reduce disease/symptoms</td>
<td>Aim to prevent disease</td>
</tr>
<tr>
<td>Population: those with a disease/symptom</td>
<td>Population: those who do not have the disease</td>
</tr>
<tr>
<td>Many case studies published about recruitment barriers and solutions</td>
<td>Some case studies published about recruitment barriers</td>
</tr>
<tr>
<td>Numerous meta-analyses/systematic assessments about recruitment barriers</td>
<td>No systematic assessment about recruitment barriers</td>
</tr>
</tbody>
</table>
Identified recruitment barriers for prophylactic vaccine trials in Belgium

Three areas of focus to improve recruitment
Survey about recruitment barriers

- Sponsor organisation: 20%
- CRO: 28%
- Public investigator site: 32%
- Private investigator site: 8%
- Other: 12%

Harrington et al., *under peer review*
Survey about recruitment barriers

Recruitment barriers: impact and frequency map

- Visit schedule
- Selection criteria
- Public knowledge of the disease
- Recruitment budget
- Human resources dedicated to recruitment
- Other protocol-related issues
- Public knowledge of clinical trials
- Training/experience in recruitment
- Trial design
- Transport access to trial site
- Vaccine hesitancy
- Disincentives of HCPs to recruit
- Consent process

Data from Harrington et al., under peer review

N=20-23
Survey about recruitment barriers

Harrington et al., under peer review

26 Sep 2017
Easy to recruit populations

Database of volunteers
- 81% of survey respondents reported that having a database of volunteers is a successful strategy

Dedicated staff for recruitment
- 86% of respondents reported that having dedicated HR for recruitment is a successful strategy

Subjects come back for future studies

Harrington et al., under peer review
Difficult to recruit populations

- Populations are dynamic
- Populations not typically found on a database
- Accessed via hospitals, clinics, other HCPs
- Recruited outside of full-time research setting
  - Fewer resources
  - Must balance care-giving activities with research activities
All populations
A decision of cost versus benefit

Cost:
- Convenience of visit schedule
- Time off work, school etc
- Getting to the trial site

Benefit:
- Motivation is altruism
- Contributing to science/medicine
- Relies on understanding the burden of disease
## Ways to improve recruitment

<table>
<thead>
<tr>
<th>Facilitate HCP participation in clinical trials of prophylactic vaccines</th>
<th>HCP networks. Sharing knowledge and resources Training in research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase public awareness of infectious diseases</td>
<td>Public campaigning Education</td>
</tr>
<tr>
<td>Increase the flexibility of clinical trials, to reduce the burden to volunteer</td>
<td>Mobile units: bringing the trial to the subject</td>
</tr>
</tbody>
</table>
Ways to improve recruitment

Increase the pool of people willing to volunteer for a prophylactic vaccine trial

Increase the probability of success in recruiting eligible people
Thank you for your attention
## The situation in Belgium

### Study

<table>
<thead>
<tr>
<th>Study</th>
<th>Subject population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1 Study on the Safety and Reactogenicity of a Single Dose of Monovalent High-dose Inactivated Poliovirus Type 2 Vaccine (m-IPV2 HD) Given Intramuscularly Compared to Standard Trivalent Inactivated Poliovirus Vaccine (IPV) in Healthy Adults</td>
<td>Healthy adults 18-45 years of age</td>
</tr>
<tr>
<td>Safety and Immunogenicity of a Trivalent Influenza Vaccine When Administered to Elderly Subjects</td>
<td>Male and female volunteers of ≥65 years of age</td>
</tr>
<tr>
<td>Pertussis Immunization During Pregnancy: Effect in Term and Preterm Infants</td>
<td>(Pre)term infants born from pertussis (un)vaccinated women</td>
</tr>
<tr>
<td>An Efficacy Study of GlaxoSmithKline (GSK) Biologicals' Candidate Influenza Vaccine GSK2321138A in Children</td>
<td>Healthy infants 6-35 months of age</td>
</tr>
<tr>
<td>Study to Evaluate the Dosage and Safety of Two Intramuscular Injections of an Investigational Clade B HIV Vaccine</td>
<td>Healthy adults 18-27 years of age</td>
</tr>
<tr>
<td>Study in Healthy Adults to Evaluate Gene Activation After Vaccination With GlaxoSmithKline (GSK) Biologicals' Candidate Tuberculosis (TB) Vaccine GSK 692342</td>
<td>Healthy adults 18-50 years of age</td>
</tr>
<tr>
<td>Influenza A/H1N1/2009-adjuvanted Vaccine in Renal Disease Patients</td>
<td>Adults with renal transplant. Stable renal function for the last 3 months</td>
</tr>
</tbody>
</table>

Source: clinicaltrials.gov 17 Sep 2017 Search terms: Vaccines, Belgium, 01/01/2011-17/09/2017