Noncommercial Funders’ Policies on Trial Registration, Access to Summary Results, and Individual Patient Data Availability

Clinical trial funders can promote transparency and prevent publication bias through clear policies.1-3 In a May 2017 World Health Organization (WHO) joint statement, funders pledged to develop policies, within 1 year of signing, that will require funded trials to be registered and reported, and improve individual patient data (IPD) sharing.4 We assessed trials transparency policies from a sample of noncommercial funders in these domains.

Methods | We examined the top 20 noncommercial funders of health research globally, by 2013 expenditure,5 against a reference standard aligned to the WHO joint statement: that all trials should be registered, summary results made available via publication or trial registries, and IPD reasonably made available whenever possible.3,4

We created audit questions that we then used to assess funders’ publicly accessible policies against these reference standards, focusing on (1) the presence of a clear policy for each area; (2) whether adherence on summary results and IPD sharing was required, or addressed only with supportive language (acknowledging the importance of the standard but not requiring consistent adherence); (3) how funders assessed trialists’ adherence; and (4) whether adherence audits were publicly available. Open access policies were not considered as results sharing policies. Table 1 shows WHO policy elements and our audit questions; no external validation was done on the audit questions.

Two researchers searched funder websites and Google from February 2017 through April 2017. Non-English material was reviewed using Google Translate. Additionally, native speakers were recruited to conduct supplemental non-English searches. Policies were extracted, assessed, and stored verbatim. Disagreements were rectified unanimously.

Funders were emailed with findings during May-June 2017 and given 6 weeks to respond, on the record, to whether they “agreed[d] with our characterisation of your organization's policies.” Nonresponders were contacted 2 more times. Descriptive statistics were generated summarizing the policies.

Results | Eighteen funders were included, as 2 stated they do not fund trials. Nine funders (50%) required all trials to be registered, 8 (44%) required all summary results reported, 4 (22%) provided specific timelines for sharing summary results, and 2 (11%) required IPD sharing. Only 2 funders (11%) had a requirement covering all domains (Table 2). Six funders (33%) offered technical or financial resources to support IPD sharing.

Table 1. 2017 WHO Joint Statement Common Policy Elements and Audit Questions Used to Assess Trial Transparency Policies of Noncommercial Funders of Clinical Trials

<table>
<thead>
<tr>
<th>Policy Domain</th>
<th>Summary Results Sharing</th>
<th>IPD Sharing</th>
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<tbody>
<tr>
<td><strong>WHO Joint Statement Common Policy Elements</strong></td>
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<tr>
<td><strong>Trial Registration</strong></td>
<td>We jointly agree that summary results of clinical trials should be made publicly available in a timely manner following primary study completion. There are 2 main modalities for this to occur. By posting to the results section of the clinical trial registry and by journal publication. We will work towards a timeframe of 12 months from primary study completion as the global norm for summary results disclosure.</td>
<td>The benefit of sharing IPD and the facilitation of research through greater access to primary datasets is a principle, which we consider important…. We will continue to engage with partners in support of an enabling environment to allow data sharing to maximize the value of health research data. We will support activities that enable the development of explicit ethical and legal frameworks that govern data collection and use and enable development of international norms and standards for sharing of IPD from clinical trials.</td>
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<tr>
<th>Study Questions</th>
<th>Yes/No</th>
<th>Yes/No</th>
<th>Yes/No</th>
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<tbody>
<tr>
<td>Do they have a policy at all?</td>
<td>Yes/No</td>
<td>Yes/No (excluding any open access policies)</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Do they require...</td>
<td>... all trials to be registered?</td>
<td>... all summary results to be made publicly available? (Yes/Supportive Statement/No)</td>
<td>... IPD from all trials to be made available (within reason)? (Yes/Supportive Statement/No)</td>
</tr>
<tr>
<td>Do they...</td>
<td>... give a timeline within which a result must be reported after completion? Yes/No</td>
<td>... explicitly provide additional technical or financial resources to support IPD sharing? Yes/No</td>
<td></td>
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<tr>
<td>Do they describe how they internally monitor adherence?</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
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<tr>
<td>Do they publish anything publicly on their audit of adherence?</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
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Abbreviations: IPD, individual participants’ data; WHO, World Health Organization.
Monitoring of trialists’ adherence was described by 7 funders (39%) in all instances, or contained only supportive language rather than a clear requirement. Overall, 7 funders (39%) met this lower criteria for sharing summary results, and 9 (50%) for IPD.

Monitoring of trialists’ adherence was described by 7 funders (39%) for registration; 6 (33%) for summary results sharing; and 6 (33%) for IPD sharing. Some funders described how they monitored adherence without mandating sharing. No funder proactively shared any adherence audit. Fourteen funders (78%) responded to follow-up; 6 of 252 data points (2%) were revised in response to funder feedback.

**Discussion** | Clinical trial transparency policies of noncommercial funders varied greatly. Most funders did not require grant recipients to register all trials, share all trials’ summary results, and share IPD. Internal procedures for monitoring adherence were poorly described, and no funder had a clear policy to disclose adherence data. As of February 2018, 6 assessed funders have signed the WHO joint statement and therefore pledged to incorporate WHO’s proposed policy elements during the coming months.

Previous narrative descriptions covering smaller samples of noncommercial sponsors’ policies, which focus broadly on transparency and resource allocation in research, are consistent with these findings. An audit of top pharmaceutical companies found more comprehensive policies requiring all trials to be registered (91%), summary results reported (96%), and IPD shared (96%).

This study has limitations. The sample contained only 18 funders; however, these accounted for $41 billion in 2013 health care research spending. No validation of audit questions was conducted; however, the questionnaire was simple
and aligned largely to WHO’s joint statement. Policies were examined rather than performance. Future work should include ongoing monitoring of changes to funders’ policies and adherence to these policies by trialists, as recommended by WHO.

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Critical revision of the manuscript for important intellectual content: All authors.

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Additional Information: All underlying data, including data on all individual funders, are available at https://figshare.com/s/276f9dc0b37d8ecd0ab0.


Trends in Obesity and Severe Obesity Prevalence in US Youth and Adults by Sex and Age, 2007-2008 to 2015-2016

Obesity prevalence has been increasing since the 1980s among adults, but among youth, prevalence plateaued between 2005-2006 and 2013-2014.1,2 We analyzed trends in obesity prevalence among US youth and adults between 2007-2008 and 2015-2016 in order to determine recent changes.

Methods | The National Health and Nutrition Examination Survey (NHANES) is a cross-sectional survey with a complex, multistage probability design that represents the civilian, noninstitutionalized population with a response rate of 75.4% in 2007-2008 and 58.7% in 2015-2016.3 Participants 18 years or older provided written consent, youth aged 7 to 17 years provided written assent, and parental permission was obtained in writing for youth younger than 18 years. NHANES was approved by the National Center for Health Statistics research ethics review board. Standardized measurements of weight and height were obtained.3

Among adults aged 20 years and older, obesity was defined as a body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) of 30 or more and severe obesity was defined as a BMI of 40 or more.4 Among youth aged 2 to 19 years, obesity was defined as a BMI at or above the 95th percentile of sex-specific BMI-for-age and severe obesity was defined as a BMI at or above 120% of the 95th percentile.3 Pregnant females were excluded.

Prevalence and 95% CIs of obesity and severe obesity were estimated overall5 and stratified by sex and age (2-5, 6-11, 12-19, 20-39, 40-59, and ≥60 years). Linear and quadratic trends overall and stratified by sex and age were examined in regression models with 2-year survey cycles modeled as an orthogonal polynomial and in adjusted models (including survey cycle, sex, age, race/Hisppanic origin [non-Hispanic white, non-Hispanic black, Hispanic, or other], education [high school graduate or less, some college, and college graduate; education of household head for youth], and, among adults, smoking status [never, former, or current smoker]) to determine if trends could be explained by these factors. Interactions between survey cycle with sex and age were tested among youth and adults separately to supplement stratified analyses and were not significant. A 2-sided P value of .05 was used to assess statistical significance.

Statistical analyses accounted for the complex survey design, including examination sample weights, which adjusted for nonresponse and took into account loss between the screenier and interviewer and between the interview and the examination. Analyses were conducted using R (R statistics), version 3.4.1; SAS (SAS Institute), version 9.4; and SUDAAN (RTI International), version 11.0.

Results | Data from 16 675 youth (Table 1) and 27 449 adults (Table 2) were analyzed. Among youth, obesity prevalence was 16.8% (95% CI, 14.2%-19.8%) in 2007-2008 and 18.5% (95% CI, 15.8%-21.3%) in 2015-2016. Based on the unadjusted model, there were no significant linear trends in the prevalence of obesity or severe obesity overall, by sex or age.