Author’s response to reviews

Title: Non-communicable diseases: mapping research funding organizations, funding mechanisms and research practices in Italy and Germany.

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You will find the reply to reviewers table in the supplementary material.

1 What is the rational for comparing Italy with Germany? The selection of countries for comparison should be justified. Thank you for this important comment. Italy and Germany appear as an interesting match to examine. Both are major EU continental countries which however developed two different healthcare systems, namely a mainly Bismarckian model in Germany (i.e. presence of Statutory Health Insurance (SHI), which is funded through contributions from employers and employees) and a Beveridge-type system in Italy (i.e. the National Health Service provides since 1978 universal coverage and it’s funded through general taxation and, in smaller part, through user charges). In terms of biomedical research ecosystems, both countries praise a track record of excellence and internationally recognized work, however with some anecdotal differences in the approach to research funding (e.g. level of private and industry-funded research activities in the German country). All these elements constituted a good reason to start a comparative analysis based on available data on research funding mechanisms and level in NCDs across the two countries.

2 At least 5 different methods are cited at different moments in the article (references 6, 7, 8, 10, 11) covering case-oriented approaches, comparative research design, inductive thematic analysis, constant comparative approach and mixed methodologies. But it is not clear exactly how these were implemented. For example, figure 1 is taken from Lor's framework in
comparative librarianship methods, which may be an inspiration for health policy comparison but does seem like an add-on since the Lor's method was not directly used - or if it was, perhaps the figure could be explained.

Since overall this seems more like a description of the two countries than a head to head comparison so it is very unclear how these comparative approaches have been implemented.

In the limitations (page 13) it states that a specific framework has been used but it is not clear which specific framework is being referred to. Thank you for this comment. Figure 1 shows where our study fits in the Lor’s framework in justification of why we have chosen a comparative research design approach with few-country comparison, a case-oriented comparative strategy and mixed methodology. However because, as you point out, the framework itself has not been used, we have now removed the figure. The head-to-head comparison is conducted on three main dimensions: 1) identification of the network of research funding organizations (RFOs) in Italy and Germany, 2) assessment of funding patterns and 3) funding distribution mechanisms. This has been done using a mixed method approach that includes review of the literature, analysis of qualitative/quantitative survey data and thematic analysis of interviews with KOLs.

3 Figure 2 is a little redundant since it essentially repeats the previous sentences (lines 49 to 53 page 4) and does not seem to be more than text. Thank you for pointing this out, we have removed Figure 2

4 An inclusion criteria for the RFOs was stated as being a minimum of 0.5 K euros invested in research (lines 12 to 14 page 5). Please clarify - is this a threshold for all research activities (non-medical included), just medical research, only NCD research or a minimum by type of NCD? Thanks for pointing this out. The threshold was set for NCD research. We have clarified this aspect in the text.
5 The data collection methods describes how the survey results were processed with percentages, proportions, averages and standard deviations (line 30, page 6). However, very little quantitative data is given in the results and no averages and standard deviations are reported. Perhaps it is best not to mention them in the methods if they are not pertinent to the article. Thank you. We have updated the results section based on this comment.

6 When one interviewee gives an opinion (line 9 page 7) it is not possible to start the sentence with "in the view of KOLs". Thank you. We have changed that to reflect that it was only one interviewee.

7 Additional table 1 title should be "included" and not "excluded". Thank you. We have edited the title of the table.

8 Some of the Italian RFOs in the additional table listed have very low research funding reported e.g. Fondazione Cassa di Risparmio di Cuneo - did these small RFOs reach the 0.5 K euros inclusion criteria? The threshold was set for NCD research. We have clarified this aspect in the text.

9 It is very interesting to have an idea of the funding spent on R&D (lines 28 to 50 page 7) but these numbers include non-biomedical spending and thus the title of the section "Funding pattern towards NCD research" is a little misleading. Thanks for pointing this out. Actually PRIN data are NCD specific but others streams are not, therefore we have modified that heading to read “biomedical and NCD research”. 
Figure 4 is interesting in that it is possible to see the relative centres of interest for the PRIN projects. However, given that the maximum annual investment is 14,000 euros, in the light of the billions spent on R&D, it is not quite important enough to include as a numbered figure. 2011 data seems to be missing from the graph. In relation to Figure 4, y-axis is expressed in 1,000EUR (kEUR), so the maximum amount funded is 14 million EUR. There was only one call for funding over the period 2010-2011, that explains why 2011 seems missing, and then again in 2012.

It is stated that a proportion 15% of the 5 per thousand entities have not made their data available (line 5, page 9) Please specify how many entities this is rather than just giving the percentage. Entities which received 5 per thousand funds linked to healthcare research have to report the data that is made available on the Department of Health website. We classified projects whose titles were directly referring to one of the five NCD disease areas of interest. A proportion of about 15% of all entities receiving funds has not made a report of available, which is equivalent to 40 to 45 institutions between 2008-2011.

Figure 6 needs to have an "n" defined. Is the number of banks included the same for each year reported? Some analysis is required - e.g. is there a reason for the outlier in 2008 with diabetes funding sky rocketing? The number of RFOs surveyed is 26 but data are sparse and missing in certain years. Moreover, some RFOs do not necessarily fund all NCD areas of research. We have added a note to clarify how many RFOs reported data on a specific year. With respect to the 2008 Diabetes outlier, this is due to one organization reporting spot funding of 5 million Euros for one project just for the year.

The paragraph under the heading of "Network of research funding organizations" carries financial data for the German case, whereas for Italy they are in the "Funding patterns towards NCD research". For reasons of comparison and ease of reading, this could be streamlined. Thank you for pointing this out. We streamlined the paragraphs and moved further financial information to the “funding pattern” section.
The conclusion alludes to advantages and disadvantages of the national research landscapes (line 11, page 15) - please detail the relative advantages and disadvantages to clarify what they are. For example, as the study says, the 5 per thousand Italian system give tax breaks to donors. Is there anything like this in Germany? Does this encourage people to donate?

Thanks for mentioning that. We enriched the discussion section with arguments related to the advantages and disadvantages of the research systems (e.g. the non-existence of an approach such as the 5 per thousand mechanism in Germany and the low donation-rate of German citizens compared to Italian citizens)

The abstract alludes to there being 4 times as many RFOs in Italy, yet the article states that there are 100s of small non-profit foundations in Germany (line 38 page 9) that were not asked to join the survey. Perhaps they do not reach the funding threshold of the study, but this could be clarified. Thanks. We clarified this and added a sentence on why we did not invite these small foundations to the survey (i.e. “The majority of identified foundations were not eligible for inclusion because of their limited investments in NCD research.”)

The article is interesting but the analysis should go beyond describing the national institutions and offer readers an overall research context. More information is needed on

A) the role, mandate and existing mechanisms for research promotion from the different institutions, if the goal is to map funding and practices.

B) It would be interesting to learn about their operations and the outcome of any special initiative

C) As the motivation for the study is to disseminate information for possible cross-country collaboration, it would be useful to assess the level of institutional international collaboration. An estimate of the extent to which the national scientific community counts on international funding would allow assessing the relevance of national sources of funding.

D) Barriers or challenges faced by the organizations in supporting funding are not addressed.

E) No analysis is done on how the institutions interact, nor on potential gaps, overlaps, synergies and opportunities as proposed in the Mapping_NCD project.
A) Mechanisms for research funding is described in the chapters “mechanisms used to distribute funding and expectations regarding outputs” (page 6/7 and 10). We added a paragraph to the discussion section where we compare the mechanisms between Italy and Germany.

B) We highlight some initiatives, such as the health centres against NCDs in Germany or the National Plan for Chronic Illnesses in Italy.

C) We added sentences regarding the international involvement into the section “mechanisms used to distribute funding and expectations regarding outputs” and we also added a paragraph in the discussion section.

D) Yes, you are right. Unfortunately, this was not part of our analysis and the questionnaire. Therefore, we can not make clear statements regarding challenges faced by the research funders. We did, however, receive information about barriers and challenges of research performers and report them in the discussion section.

E) We added paragraphs regarding the international cooperation level of the funding agencies and conclude that there must be overlaps of research funding since there is no appropriate coordination both within the EU and between Italy and Germany.

F) Thank you for pointing this out. We rewrote and improved the discussion section.
justify the selection of Italy and Germany for the study  

18 Give some background in terms of existing national research system, research policy and/or research governance. An overview of the national research system is given in first sections of the country cases. The focus is on research funding institutions and the important actors. Their funding patterns etc. are described in the subsequent sections.

figures 1 and 2 can be excluded:  

20 explain how the literature review and selection of organizations were done  
Thank you, we have added details on how the literature search was conducted.

21 explain how the cut-off funding for inclusion was defined  
Thank you for this comment. A baseline threshold of €0.5 million in annual investment has been set with the goal of identifying funding that could be expected to influence the content or direction of major research programmes. A Reference has been added to Brigham et al. 2016.

inform how the key opinion leaders were selected and their role in the RFOs  
Thank you. A sentence on this had been added to clarify KOLs’ selection.

describe/discuss the balance between public and private funding  
Thank you. We discuss now the level of engagement private and public entities in research funding in Italy and Germany.
24 a table with side-by-side country comparison of the different characteristics of research institutions would facilitate the reader. Thank you for the comment. We included a table to synthetize the by-country comparison according to main parameters.

25 explain which other approach could be used in the comparison as mentioned. We are now mentioning a different approach in the limitation section (estimating funding activities by counting and analyzing publications (bibliometric analysis))

26 the conclusion refer to "cross-country and system comparison", although the description is segmented without cross-country or system discussion. Thank you. We have reworded that sentence in order to be more specific.

27 some statements of the discussion does not seem to be derived from or related to the objectives of the study (i.e. the "European layer" comments or the "ability to coordinate large multinational trials for CVD") Thank you very much. We tried to make the conclusions more precise and strictly depending on our findings.

28 relevant aspect of the research-funding mapping, which was not addressed in the study, would be the perception of the final users of funds (investigators and research institutions). This perspective would add essential knowledge when discussing cross-country collaboration. Thanks for raising this point. We focus on the providers of research grants in this study (i.e. research funding organizations), but interviewed KOLs raised also concerns on the users of funds. We included a paragraph about the perception of researchers in the discussion section.