Further to reviewing the oral evidence session on 4th December, I would like to clarify three points:

1) The REWARD Alliance

Scientific research is only useful if the results – either positive or negative – are reported accurately. Studies have shown that at least 85% of all health research is wasted because it “asks the wrong questions, is badly designed, not published or poorly reported”\(^1\). **This is the most significant integrity issue in contemporary science, far more serious and widespread than scientific fraud.**

The issue was highlighted in a series of five papers published in the Lancet in 2014\(^2\), which made 17 recommendations for how to increase value and reduce waste in research. Subsequently, a conference was held in Edinburgh in September 2015 that established the REWARD Alliance (Reducing Waste And Rewarding Diligence) to promote these recommendations. The following REWARD statement was formulated:

> “We recognise that, while we strive for excellence in research, there is much that needs to be done to reduce waste and increase the value of our contributions. We maximise our research potential when:

> • we set the right research priorities;
> • we use robust research design, conduct and analysis;
> • regulation and management are proportionate to risks;
> • all information on research methods and findings are accessible;
> • reports of research are complete and usable.

> We believe we have a responsibility not just to seek to advance knowledge, but also to advance the practice of research itself. This will contribute to improvement in the health and lives of all peoples, everywhere. As funders, regulators, commercial organisations, publishers, editors, researchers, research users and others – we commit to playing our part in increasing value and reducing waste in research.”

To pursue this ideal five REWARD working groups have been set up: a research funders group, an editors and publishers group (led by Liz Wagner), a research institutions working group, a “Research on Research” working group, and a regulators and funders working group led by myself and Dr Hugh Davies.

**Endorsement of the REWARD statement in the final report by the committee and/or by the minister would significantly assist the task of promoting this central issue in research integrity.** The committee could also encourage other groups such as Universities UK or funders to endorse and reference the REWARD statement.

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\(^1\) Chalmers, Iain et al. (2009) *Avoidable waste in the production and reporting of research evidence* The Lancet, Volume 374, Issue 9683, 86 - 89

\(^2\) http://www.thelancet.com/series/research
2) On conducting audits using research ethics committee records held by the Health Research Authority:

As discussed in the oral session and in a number of earlier written submissions (RIN0022, RES0008, RIN0080), the records held by the Health Research Authority (HRA) represent a fantastic source for auditing research conducted in the NHS or subject to certain regulations. However, any audit needs to achieve 2 aims:

1) Determine what studies have taken place and whether any results have been posted (to address the problem of “publication bias”)

2) Determine whether the results posted represent the original aim of the study (to address the related problem of “outcome reporting bias”)

As stated by Dr’s Goldacre and Lane at the oral evidence session on 4th December, it could be relatively cheap and easy to address the first problem - publication bias - by allowing automated software produced by Dr Goldacre to analyse records held by the HRA. But this only solves less than half of the problem. Determining whether results have been posted does not address whether they appropriately represent the study that was actually conducted. In order to address this second issue a comparison needs to be made between the original documentation (held by the HRA) and the final study reports (no matter where these reports have been published/posted). It is only when this comparison has been made that we can determine whether the research adds to the scientific literature or adds to research waste.

In the audit described in my 2015 paper\(^3\) we analysed both publication AND outcome reporting bias. It was the outcome reporting bias aspect that took the most effort and would require additional resources. This was pointed out by Janet Wisely (CEO of the HRA) in our joint 2017 “Head to Head” discussion on this topic in the British Medical Journal\(^4\). Janet also commented that the audit role should not be a task for ethics committees, but I have never proposed that ethics committees themselves perform the audit. Instead, as stated in my earlier submission (RIN0022):

b8 We therefore argue that the HRA need to do more to support the ethics process by effectively monitor publication and outcome reporting bias using REC records. Our pilot work suggests a method that could be used to provide definitive publication data for all research conducted using NHS patients and resources that submit to RECs in England...

b9 The question of funding for a number of posts to analyse this data would not necessarily need to be met directly by the HRA as almost all significant research funders, sponsors and even city investors have already indicated their interest in ensuring research transparency through signing up to the AllTrials campaign. The HRA could therefore approach these other bodies for a shared contribution towards the cost of running such an operation.

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b10Perhaps the only significant question would be what to do once the results are in and sponsors/researchers who do not publish are identified. It may be hoped that if researchers know that this data is being gathered, higher levels of publication may result, but if publications are not forthcoming the HRA will be in an excellent position to contact researchers and find out why...

Finally, on this point, I appreciate the comments made by Dr’s Goldacre and Lane that clinical trials represent the “canary in the cage” as they are a relatively tractable problem given the existence of research registries and shared regulatory frameworks. But, clinical trials of investigative medicinal products represent only 16% of research conducted in the NHS. Limiting action to clinical trials will only barely address the estimate made by members of the REWARD Alliance that 85% of ALL health research is wasted.

3) The state of research ethics committees today

I was slightly concerned to read comments made about research ethics committees in the additional written evidence (RES0025) submitted after one of the earlier oral hearings. On page 2, in relation to a misconduct case, a distinction is made between “Local Research Ethics Committees” and “Multicentre Research Ethics Committees”. It should be noted that this arrangement was abolished about ten years ago, and since then the Health Research Authority has been established as an executive non-departmental public body (NDPB) with a role that includes the national coordination of research ethics committees. As a result, the regulation and oversight of research ethics committees has improved significantly over recent years based upon ever improving governance arrangements and standard operating procedures. It is of note that many “horror stories” relating to ethics committees are circulating, but very few of them are contemporary. Those that are contemporary are swiftly investigated by the HRA.

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5 An updated to the 2009 estimate, still agreeing with this figure, was published by the original authors on the BMJ blog in 2016 see http://blogs.bmj.com/bmj/2016/01/14/paul-glazsiou-and-iain-chalmers-is-85-of-health-research-really-wasted/
