Poor quality data is informing the future of our patient care, warns study

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An investigation into how patient outcomes are assessed in clinical trials has revealed a worrying lack of consistency, raising concerns about funding being wasted on the acquisition of poor quality data.

Information collected through clinical trials plays a crucial role in improving the standard of patient care. Patient Reported Outcomes (PROs) inform our understanding of how certain treatments and interventions work by evaluating their effectiveness, and any potential side effects, from the patient perspective.

Patients in trials are commonly invited to fill in questionnaires about pain, symptoms or other effects on their quality of life.

Research published in *PLOS ONE* paints a picture of inefficient practice in the design of clinical trials which include PROs. The authors have called for new, streamlined recommendations on how PRO data should be collected.

Professor Melanie Calvert, from the University of Birmingham, explained, "Researchers face a difficult task in designing effective clinical trials that include PROs. It took our team over six months to trawl through over 20,000 papers to find the relevant guidance documents; guidance is hard to access and inconsistent."

Within these documents, the team found 162 separate PRO recommendations. Only five (3%) appeared in more than half of the

documents, adding to the confusion. Unsurprisingly, in a separate *PLOS ONE* publication led by Professor Calvert and Dr Derek Kyte, it was shown that the design of PRO data collection in trial protocols is substandard.

Professor Calvert added, "The discrepancies in how we carry out data collection poses a real problem, data needs to be collected in a consistent manner otherwise we are at risk of seeing poor quality data that is potentially biased."

"The funding available for clinical trials is simply not large enough that we can afford to waste it on collecting biased data. The concern is twofold; that the data will be unusable or, perhaps more worryingly, that potentially biased and poorly acquired data is used to inform policy decisions and the future of patient care."

Maria von Hildebrand, a patient advocate and a lay advisor for the Clinical Trials Gateway, said, "'Further research into streamlining the collection of patient outcomes in clinical trials is clearly needed to encourage publication of results, improve clinical practice and to inform patient care"

"The patient perspective is such a valuable resource. To make the best use of it, we need a more holistic and straightforward set of guidelines."

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