International Journal of Population Data Science

Journal Website: www.ijpds.org

Unconsented linkage between dormant trials and administrative data: practical and regulatory implications

Verfuerden, M[1], Fewtrell, M[1], Kennedy, K[1], Lucas, A[1], Jerrim, J[2], Harron, K[3], and Gilbert, R[1]

[1]UCL Great Ormond Street Institute of Child Health

[2]UCL Institute of Education

[3]University College London

Introduction

Half of all infants are fed formula milk. However, attrition biases evidence on the long-term safety of formula ingredients. We used unconsented linkage between administrative education and health records of young people who were randomised as infants to formula milks, to determine long-term safety and efficacy.

Objectives and Approach

We used record level data from a series of 9 historical randomised controlled trials (RCTs) conducted in 1982-2002 (n=3,500 participants), which are key to the evidence-base around formula-composition. All later follow-ups are biased by attrition leading to limited evidence around the long-term effects of formula ingredients on cognition and metabolic and cardiovascular health. We sought permissions from data providers and regulatory agencies for unconsented linkage to education and hospital records, as proxy measures for cognitive and health development. We discuss the steps that were implemented to safeguard the participants' privacy and achieve ethical and multi-institutional approval for this project.

Results

Achieving provisional ethical approval took 41 days. Achieving agreement in principle to match trial data to individual level education records took 4 months and 2 weeks, while agreement to match trial data to individual level hospital records is still underway (5.5 months in February 2018). Delays in institutional approval were largely due to unharmonised data security certificates between the two government departments holding the health and education records. Digitising and cleaning all handwritten RCT participant identifiers prior to linkage took 9 months of full-time researcher time. Maintaining separation of identifiers and attribute data required specific secure haven provision. Results on the success of linkage between RCTs and education records will be presented at the conference.

Conclusion/Implications

While directly contributing to the evidence around infant-formula-composition, this project will also act as a proof-of-concept study. Unconsented linkage between dormant RCTs and administrative data could be a novel and cost-effective method to generate evidence on the long-term efficacy and safety of interventions.

http://dx.doi.org/10.23889/ijpds.v3i4.731