Better Patient-Level Evidence:
The Value of Data Unification

Overview

There is a growing number of healthcare trends with a universal effect on citizens of the globe, such as

- Increased ageing and frailty
- Increased incidence of long-term conditions
- Increased complexity of care
- Increased use of technology
- Increased health improvement expectations
- Rising cost of healthcare treatments
- Pressure on existing healthcare resources and systems
- Pandemic preparedness

In order to manifestly improve global health outcomes, it is clear we need to do things differently.

At **FITFILE**, we support the view that the unification of patient-level data across many unconnected data silos is essential for creating a complete, single view of relevant evidence for better research, planning and care to address these major trends.[1]

Outcomes

Key strategies for improving outcomes centre around improved unification of data across the multitude of validated health and activity-related data sources, and utilising these united data to

- Power and enhance research outputs
- Inform healthcare planning initiatives
- Improve direct care provision

The need for scale and completeness

Interestingly, uniting only healthcare records provides rather limited real-world evidence since clinical and genomic factors typically constitute merely 40% of the key determinants of health outcomes. Exogenous factors such as behavioural, social and environmental make up a larger 60%[2] of the key determinants.

Traditionally, this information is not held in medical records and not easily accessible nor integrated, and it should therefore start to be properly tracked and united with information from the healthcare domain.

More technically speaking, it can be assumed that the multivariate analyses tracking these outcomes should be a) of sufficient scale of sample size for strong statistical power, and b) correctly specified with the right independent variables (i.e. clinical and non-clinical metrics) in order to reliably predict the dependent variable (i.e. outcomes). If this is not the case, which is to say that too few (or, less commonly, too

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[1] How healthcare organisations can use data unification to find insights, Health Data Management, 2017

[2] Real-world evidence: From activity to impact in healthcare decision making, McKinsey, 2018

many) of the relevant health and activity metrics are tracked, this means the overall outcome is either insufficiently or incorrectly characterised. We show this below, where adding more individuals ("scale") always improves the result, but adding ever more metrics ("completeness") eventually reduces the quality of the result due to issues such as redundant variables creeping in.

Quality of Evidence

Longitudinal systemic view

At present. attempts at bringing together data for enriched insights and research over a longitudinal timeframe tend to be one-off, encumbered by interoperability challenges and costly consent processes. We believe that uniting data silos results in the development of a longitudinal systemic view which offers a breadth and depth of insights that currently is not the standard. Our view is that this longitudinal systemic view should be the "norm".

The importance of a longitudinal view cannot be overstated. It allows researchers to detect developments or changes in the characteristics of a target population at both the group and individual level[3]. This facilitates accurate tracking of real-world outcomes and, for instance, provides additional insight following on from randomised controlled trials or other pre-launch studies on therapeutics, devices and diagnostics.

Benefits

A key benefit of data unification can be the creation of reference databases for superior data-driven decision-making.

An outline of some of the specific benefits of data unification by user group follows below.

Individuals will have a fuller view and deeper understanding of their own health and wellbeing, empowering them to take a more active part in its management. This can motivate and incentivise individuals to adopt positive lifestyle practices as seen with the advent of fitness and lifestyle trackers, thereby improving some chronic conditions and acting as a preventative measure as well.

Clinicians can better understand their patients and make the most informed decisions based on a "truer" real-world view of their patients. They can better assess

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[3] Strengths of longitudinal data, UCL Institute of Education, 2020

response to treatment as well as ensure visibility and alignment of treatment across healthcare professionals in community, primary and secondary care.

Improved management is particularly useful for long-term conditions which internationally affect between 22-57% of individuals[4] and can constitute up to 80% of total healthcare spend.

Commissioners, payors and regulators utilising enhanced population level stratification are able to better understand population needs and population flows, and have greater ability to track the impact of any service or operational changes to pathways. They are also able to accurately identify the population groups who are most at need and present the highest cost to the system, therefore being better able to appropriately support them through pathway change, personalised care plans and the use of patient support programmes.

The day-to-day advantages will accrue through a reduction in acute exacerbations, acute presentations at healthcare service providers and a reduction in unplanned admissions. The resultant system-wide savings can be reinvested to address other key areas of need. In the UK for instance, the annual costs of long-term condition

emergency admissions run to £10bn, with the potential for £4bn savings through improved healthcare planning with enhanced insights[5].

Researchers and research organisations benefit from data unification and regulatory-grade real-world evidence through better understanding of real-world outcomes and enhanced, directly actionable insights. A more nuanced understanding of patient phenotypes and responses to therapeutics and devices leads to development of personalised treatment options as just one example.

Industry users[6] can benefit from data unification in four key areas

Market access	Medical affairs
Epidemiology	R&D

- Market access: stronger evidence for health economic outcome research (HEOR) and reimbursement purposes
  - o Provides a more granular net system cost impact of treatments
  - o Supports longitudinal value-based healthcare evidence generation
  - o Supplies compelling support for formulary positioning

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[4] Statista, Prevalence of long-term conditions, 2018

[5] NHS England, The Health Foundation & FITFILE analysis

[6] Creating value from next-generation real-world evidence, McKinsey, 2020

- Medical affairs: higher quality scientific support
    - Generates dependable supplement insights to RCTs on efficacy and safety
    - Enhances commercial positioning and messaging
    - Provides support for enhanced labelling
- Epidemiology: richer human intelligence
    - Deeper natural history/ patient pathways
    - Fuller patient/ disease demographics
    - More detailed cost and scope of management
- R&D: smarter development opportunities that provide
    - More accurate patient heatmaps
    - Targeted patient recruitment for clinical trials
    - Intelligent tracking of desired signals

Why FITFILE?

At **FITFILE**, our mission is to deliver complete patient-level evidence, safely and efficiently.

We have developed proprietary technology and combined it with key processes in order to deliver on a uniquely complete form of GDPR-compliant data unification which is safe, secure and scalable.

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