Title: Forming norms: Informing diagnosis and management in sports medicine

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Summary

Clinicians aim to identify abnormalities, and distinguish harmful from harmless abnormalities. In sports medicine, measures of physical function such as strength, balance and joint flexibility are used as diagnostic tools to identify causes of pain and disability and monitor progression in response to an intervention. Comparing results from clinical measures against 'normal' values guides decision-making regarding health outcomes. Understanding 'normal' is therefore central to appropriate management of disease and disability. However, 'normal' is difficult to clarify and definitions are dependent on context. 'Normal' in the clinical setting is best understood as an appropriate state of physical function. Particularly as disease, pain and sickness are expected occurrences of being human, understanding 'normal' at each stage of the lifespan is essential to avoid the medicalisation of usual life processes. Clinicians use physical measures to assess physical function and identify disability. Accurate diagnosis hinges on access to 'normal' reference values for such measures. However our knowledge of 'normal' for many clinical measures in sports medicine is limited. Improved knowledge of normal physical function across the lifespan will assist greatly in the diagnosis and management of pain, disease and disability.

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Clinicians aim to identify abnormalities, and distinguish harmful from harmless abnormalities.[1] In sports medicine, measures of physical function such as strength, balance and joint flexibility are used as diagnostic tools to identify causes of pain and disability and monitor progression in response to an intervention. Comparing results from clinical measures against 'normal' values guides decision-making regarding health outcomes. Understanding 'normal' is therefore central to appropriate management of pain and disability.

Dividing populations into 'normal' versus 'diseased' largely overlooks the heterogeneity of the healthy population.[2] Particularly as disease, pain and sickness are expected occurrences of being human, understanding 'normal' at each stage of the lifespan is essential to avoid the medicalisation of usual life processes.[3] However, 'normal' is difficult to clarify and definitions are dependent on context.

In clinical settings 'normal' is used in various ways and this can lead to confusion. 'Normal' is used to describe both an *average* and a *disease-free* state. Normal as the average may mislead, because it does not necessarily reflect normal physiology.[4] For example, overweight and obesity are now the average 'norm' in many countries, but are associated with greatly increased health risks- thus 'normal' (as average) is not associated with the disease-free state. On the other hand use of 'normal' to describe a completely disease-free state can also be problematic because benign variation may be considered abnormal. For example a meniscus may be pristine (disease-free) or be 'degenerate' (no longer disease free) and this 'disease' may be evident on MRI but may have absolutely no clinical significance-like 'wrinkles with age.'[5]

Normal: an appropriate state of physiological FUNCTION

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'Normal' is best understood as an appropriate state of physiological function.[4] This clinical definition corresponds to the range of results for a particular diagnostic test or physical measure outside which disease is likely present. With regard to the musculoskeletal system, responsible for producing movement, 'normal' describes an appropriate state of physical function.

The World Health Organization recognises three levels of human functioning: the body part, the whole individual, and the individual in a social context.[6] Disability involves dysfunction at one or more of these levels. Thus, knee osteoarthritis may cause pain, muscle weakness and joint stiffness, limit walking and stair-climbing, and in turn affect the person's ability to partake in daily life. The key concern for clinicians is whether the individual can continue to participate independently in daily life, and if the abnormality in question is hindering this ability.

Understanding normal ageing

The ageing process involves complex adaptations to physical, social and psychological changes across the lifespan.[7] Physiological systems develop rapidly during early years, peak during maturity, and decline gradually with age. Systems adjust within a dynamic state to maintain health, but the ability to adapt to change diminishes in later life.[8]

When are age-related changes no longer considered 'normal'? When do 'normal' changes in the musculoskeletal system become 'disease', and at what point is intervention warranted? Osteoarthritis and other musculoskeletal disorders increase in prevalence with age and may be seen as 'part and parcel' of the ageing process. If we limit 'normal' to the optimal state all age-related changes become abnormal. Clearly that is unacceptable for individuals and society.

Quantifying 'normal'

Clinicians and researchers alike measure physical function to identify individual impairments and activity limitations. Physical measures also act as biological markers of ageing and are associated with quality of life, disability and mortality.[9] Accurate use of clinical measures is dependent on knowledge of the corresponding 'normal' reference range. Yet our knowledge of 'normal' for many measures in sports medicine is limited.

Reference values provide a 'normal' point of comparison with which to compare results from diagnostic tests and clinical measures, aiding diagnosis and management of disease and disability. Yet there are few comprehensive reference datasets for many measures of physical function. Reference values for physical measures must be stratified for factors such as age, gender and body size due to their effects on physical function. Existing data are limited to discrete aspects of physical function or constrained by small or biased samples. Reference data collected from young adult disease-free 'control' participants greatly limits the generalisability of these data to children, older adults or individuals with benign abnormalities.

Improved knowledge of normal physical function across the lifespan will assist greatly in the diagnosis and management of pain, disease and disability. This can only be achieved through development of large-scale reference data stratified for age and gender collected from a representative sample of the 'normal' population. When 'normal' is understood as an appropriate state of function, rather than an average or ideal state, progress can be made towards identifying meaningful impairments, targeting interventions and achieving better patient-centred outcomes.

Contributors and Sources

The 1000 Norms Project Consortium was established in 2012 to create a framework for the 1000 Norms Project. Jennifer Baldwin BAppSci(Phty)Hons and Joshua Burns PhD contributed to the concept, design and construction of the final draft of the manuscript. Marnee McKay MHlthSci(Sports Physio) , Claire Hiller PhD, Jean Nightingale PhD, Niamh Moloney PhD, Paulo Ferreira PhD, Milena Simic PhD and Kathryn Refshauge PhD, contributed to the concept, design and review of the final draft of the manuscript.

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Competing Interests

The authors have no competing interests to declare.

Reference List

- 1. Moynihan R, Doust J, Henry D. Preventing overdiagnosis: how to stop harming the healthy. BMJ 2012;**344**:e3502
- 2. Rowe JW, Kahn RL. Human aging: usual and successful. Science 1987;237(4811):143-49
- 3. Leibovici L, Lièvre M. Medicalisation: peering from inside medicine. BMJ 2002;**324**:866 doi: 10.1136/bmj.324.7342.866.
- 4. King CD. The meaning of normal. Yale J Biol Med 1945;17(3):493
- 5. Risberg MA. Degenerative meniscus tears should be looked upon as wrinkles with age—and should be treated accordingly. Br J Sports Med 2014;**48**(9):741 doi: 10.1136/bjsports-2014-093568.
- 6. WHO. Towards a common language for functioning, disability and health. Secondary Towards a common language for functioning, disability and health
- 2002. <u>http://www.who.int/classifications/icf/icfbeginnersguide.pdf?ua=1</u>. 7. Peel N, Bartlett H, McClure R. Healthy ageing: How is it defined and measured? Australas J Ageing
- 2004;**23**(3):115-19 8. Rattan SI. Healthy ageing, but what is health? Biogerontology 2013;**14**(6):673-7 doi: 10.1007/s10522-013-9442-7.
- 9. Cooper R, Kuh D, Hardy R, Mortality Review G, Falcon, Teams HAS. Objectively measured physical capability levels and mortality: systematic review and meta-analysis. BMJ 2010;**341**:c4467 doi: 10.1136/bmj.c4467.