STATE OF THE ART
REVIEWSGarry Egger, AM, MPH, PhD, John Stevens, PhD, RN, and
Christopher Ganora, MBBS, BMedSci, MPH, FRACGPEstablishing Proof of Concept
for Clinical Processes in Lifestyle
Medicine

Abstract: *Lifestyle medicine is a relatively new discipline, designed to improve the management of lifestyle and environmentally induced chronic diseases. As such it is evolving new skills, tools, and procedures. But these are often not assessed for their potential before being adopted in practice. Proof of concept (PoC) is an initial stage of testing characteristic of new product or process development in the commercial world. It can be equally applied to new processes and practices in lifestyle medicine.*

Keywords: lifestyle medicine; proof of concept; shared medical appointments; medical procedures

**Introduction: The
Structure of Lifestyle
Medicine**

We have previously proposed a structure and methodology for lifestyle medicine (LM) in this journal that encompasses the epidemiology (the science) of modern chronic disease, as well as the evolving skills (the art), tools (the materials), and procedures (the actions) that are appropriate for clinical practice.¹ The latter (processes or procedures) are fundamental to LM

in that they can vary from, and add to, conventional clinical procedures, for example, medication, surgery, physical therapies, and so on. On occasion, however, they are introduced without verification of their potential benefit in chronic disease management (eg, self-help websites, targeted programs for weight loss and other conditions, shared care, etc). Proof of concept (PoC) testing could validate a new idea before it is proposed for widespread use.

com/definition/
proof-of-concept-POC)

The intention of PoC testing is to provide documented evidence that a potential product or service can be successful, with minimal risk and a determined scope and effort. PoC testing is not to be confused with pilot testing, which is a test of a final process, albeit on a smaller scale, before full commitment to a scale-up and roll-out to a target audience.

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Proof of Concept Testing

Used as a standard procedure in the commercial world for new products or processes, PoC is defined as:

... realisation of a certain method or idea to demonstrate its feasibility, or a demonstration in principle, whose purpose is to verify that some concept or theory has practical potential. (<http://searchcio.techtarget.com/definition/proof-of-concept-POC>)

In the medical sphere, PoC is a standard practice in the development of new drugs and medical devices. It is often absent in the development of *lifestyle prescriptions*, however, that are required to keep up with new patterns of disease in rapidly evolving societies.² This is topical at the moment since LM is emerging as a discipline in chronic disease management.^{3,4} Although there are efforts to define a structure for LM,¹

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Table 1.

Proof of Concept (PoC) Check List.

Questions Related to the Procedure	Y	Measures
1. Is it structured around sound evidence-based principles?		Evaluative research; expert advice
2. Does it do what it claims to do for representatives of the target population?		Outcomes measures; questionnaire responses
3. Is the retention rate over time adequate?		Data records
4. Does it result in positive changes in health parameters?		Outcome measures; questionnaire responses
5. Is it enjoyed and valued by participants?		Questionnaire responses
6. Is it enjoyed and valued by providers?		Semistructured interviews
7. Would participants recommend the process to others?		Questionnaire responses; focus group evaluations
8. Do patients rate this, at least as highly for this problem, as the standard comparative process?		Questionnaire responses; focus group evaluations
9. Is it cost- and time-effective for the clinic and participants?		Economic analysis
10. Are other health care providers likely to adopt it?		Survey analysis
11. Is the target audience big enough and the potential demand great enough to justify and sustain it?		Market analysis
12. Does it reach a wider patient audience than the standard comparative process?		Demographic/psychographic analysis
13. Does it incorporate the advantages of a standard comparative process?		Process analysis
14. Does it reduce any disadvantages of a standard comparative process?		Process analysis
15. Is it time efficient for participants and providers?		Questionnaire responses

which has a basis in logic, and a foundation in epidemiology, it is currently lagging in novel skills, tools, and procedures that would differentiate it from standard modern clinical practice.

Potential Examples for PoC Testing

As well as *lifestyle prescriptions*, there are novel clinical processes being regularly proposed (eg, “de-prescription,” online training, self-help groups, telephone counseling and triaging, group therapy, psychogenetically determined behavioral scripts, etc), which are already initiated into practice with little proof of feasibility or verification of concept within

the target environment. This also applies to larger contextual changes in the medical system, such as some components of new health care initiatives.

We have faced this challenge in Australia with the introduction of Shared Medical Appointments (SMAs)^{5,6} and Programmed Shared Medical Appointments (PSMAs) in a specific topic (eg, weight control) as an adjunct process to standard 1:1 medical consultation for chronic disease management. We have experienced barriers in funding to test the process because of a lack of local evidence to support its use, something that will only come from testing the process—the classical “Catch 22” situation!

It is ironic that there is no evidence in the literature proving the benefits or otherwise of 1:1 consulting, even though this has been the standard form of provider-patient interaction for centuries. This ignores the fact that health provision is dynamic and that modern chronic diseases may require a different provider-patient interaction process than the injury and infectious disease interactions that were more prominent in the past. A belated “PoC” test of such a consulting interaction would undoubtedly show up its deficiencies for dealing with the ~60% of current clinical presentations that now involve chronic diseases.

To overcome this hiatus, we have developed a check list of items relating to the process in question to determine PoC for lifestyle-related prescriptions. We propose that all, or most of the questions shown in Table 1 need to be answered in the affirmative before any new process proceeds to a pilot phase, or is adopted in clinical practice.

Other examples of skills, tools, and actions for LM include telephone triaging, psychogenetically determined behavioral scripts, de-prescription, lifestyle “nudging,” health coaching, and many more.

Summary

The practice of LM is a work in progress. With new skills, tools, and procedures being adapted or developed for the discipline, there is a need for techniques for measuring their feasibility before these are adopted. PoC testing allows LM to lead the way in the introduction of new procedures in a transformed era of clinical practice. It

also offers opportunities to ensure the discipline is not distracted by processes such as 1:1 consulting that had historical precedent but lacks background support.

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Not applicable, because this article does not contain any studies with human or animal subjects.

Informed Consent

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Trial Registration

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References

1. Egger G. Defining a structure and methodology for practice of lifestyle medicine [published online September 20, 2016]. *Am J Lifestyle Med*. doi:10.1177/1559827616669327.
2. Sanders JW, Fuhrer GS, Johnson MD, Riddle MS. The epidemiological transition: the current status of infectious diseases in the developed world versus the developing world. *Sci Prog*. 2008;91(pt 1):1-37.
3. Rippe JM. *Lifestyle Medicine*. 2nd ed. London, England: CRC Press; 2012.
4. Egger G, Binns A, Rossner S, Sagner M. *Lifestyle Medicine: Lifestyle, the Environment and Preventive Medicine in Health and Disease*. 3rd ed. London, England: Academic Press; 2017.
5. Noffsinger EB. *The ABC's of Group Visits: An Implementation Manual for Your Practice*. New York, NY: Springer; 2010.
6. Stevens J, Cole MA, Binns A, Dixon J, Egger G. A user assessment of the potential for shared medical appointments in Australia. *Aust Fam Physician*. 2014;43: 804-807.