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A template to develop humanized technologies that meet true clinical needs^{*}

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1. The integration of people, ideas, resources, and technology

A car, for example, did not begin immediately with the design of a “four-wheeled” vehicle frame, but rather as a solution to how to solve the problem of “transporting people and objects from destination A to destination B.” This process began with the addition of wheels to a wooden plank to move heavy objects – the first dolly carts. This was followed by bicycles, motorcycles, cars, and even more complex variants, such as vehicles used in shipping and aviation. The appearance, design, and technical specifications of these vehicles are very different, but they were all created to solve the same problem of transporting people and objects.

Dolly carts were not the first solution to the transportation problem however. Between 5100 and 5300 years ago the oldest wooden wheel was discovered in what is now Slovenia.¹ Even earlier, during the Palaeolithic era (15,000–750,000 years ago), humans discovered that heavy objects could be transported on top of a fallen tree by rolling the tree beneath the objects.² The observation that a round object could assist in the movement of heavy objects is therefore the first and crudest solution of the problem of “transporting heavy objects from A to B.” All future solutions were derived from this initial solution through continuous product upgrades.

In the medical field, the development of the stethoscope is a good example of this process of innovation. As early as the late 1700s, auscultation was already an important diagnostic tool. To identify cardiopulmonary abnormalities, physicians directly placed their ears on or used their hands to tap the chests of patients. In 1816, the French physician Laënnec felt uncomfortable while examining the chest of a young woman with heart problems.³ Having been inspired by children's games, he thus decided to listen to the woman's heart sounds through a piece of paper that had been rolled into a tube. He subsequently discovered that the heart sounds were much clearer. Later, he used wood that had been shaped into a hollow cylinder to create the first

stethoscope. In 1851, the Irish physician Arthur Leared developed the first binaural stethoscope model,³ which was put into mass production the following year by George P. Camman of New York. In 1961, Professor David Littmann, a cardiologist at Harvard Medical School, designed a stethoscope to filter outside noise and to detect both high and low frequencies.⁴ In 1963, he applied for a patent and established a joint company. In 1967, 3 M acquired his company and later became the top producer of stethoscopes in the world.

This same process of product evolution based on new technologies to solve clinical problems can be observed over and over again in all fields of medicine, including imaging. One important clinical problem in imaging is to detect and monitor vertebral height loss in patients with osteoporosis.

In 1993, Professor Harry K. Genant, a radiologist at the University of California, San Francisco, successfully employed a simple visual scoring system to structure reporting of vertebral height loss, proposing that a 20% reduction in vertebral height be considered a compression fracture.⁵ However, Genant grading is subjective, non-validated, and has been challenged.⁶ In the late 1990's, rule-based software adapted the Genant scoring system to quantify the degree of vertebral height loss on DXA scans. The software has been updated over the years, and to this day it continues to be widely used.

Now, twenty years later, new research describing the automatic opportunistic detection of vertebral height loss on abdominal CT scans using AI technology has emerged.⁷ While such detection relies on new technologies, the core concept remains the grading method developed by Dr. Genant.

2. Identifying true needs requires keen observation

R&D personnel believe that the identification of “pain points” is fundamental to solving sophisticated problems. The identification of such “pain points” relies on keen observations made by experienced

^{*} Throughout history, the development of new products and technologies has come as a reaction to unmet needs. Over time, products are upgraded and evolve, resulting in more refined solutions to the same need. Each step forward offers a small improvement and therefore a more and more optimal solution to the initial unmet need. This process continues indefinitely until the perfect solution is reached.

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clinicians followed by innovative thinking regarding solutions. This requires a broad professional background, and therefore not just an ordinary medical worker, but an expert among experts.

More than a century ago, Henry Ford said that the best way to find unmet needs is to observe the problem, not to ask stakeholders or users. Taking minimally invasive surgery as an example, the robot arm system was developed after observing hundreds of operations and identifying unsatisfied needs during laparoscopic surgery that included greater stability and precision without diminishing the quality of surgical outcomes. Keen observation is the key to success. If R&D is carried out before true needs are determined, it will be unsuccessful.

3. Dehumanized R&D will not be successful

Technology derives from human nature, and so dehumanized products will all eventually fail. For example, high risk reminder pop-ups on computer screens during outpatient clinics aim to offer friendly reminders with the goal of error prevention. However, the large number of notifications often leads to fatigue. Many AI products are geared toward healthcare process management such as reducing no-shows or system scheduling, and therefore neglect the physician's perspective.

Quality medical products must be inextricably linked with human professional judgment. In the near future, AI diagnoses will require confirmation by a human physician. Purely machine based decisions for individual patients are therefore a longer term goal.

Successful product development follows a predictable evolution. Whether it is moving objects effortlessly from A to B, auscultating heart sounds more clearly, or identifying vertebral compression fractures, the process begins with the identification of a core human problem. In this way, wheels have evolved into cars, paper tubes into stethoscopes, and the Genant grading method for quantifying vertebral height loss into automated AI software for the opportunistic detection of vertebral compression fractures.

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Authors' contributions

W.P.C has made a substantial contribution to the concept or design of

the article. M.M.Y and R.O.K have made a substantial contribution to the literature review and interpretation of the relevant literature for the article. W.P.C drafted the manuscript. M.M.Y and R.O.K revised it critically for important intellectual content. All authors approved the version to be published. All authors agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Declaration of competing interest

All authors claimed no relevant disclosures.

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