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How medical practice evolves: Learning to treat failing hearts with an implantable device

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ABSTRACT

In this article we propose that medical practice evolves as a result of progress along three different pathways: improvement in the ability to develop effective medical technologies, learning in medical practice, and advances in biomedical scientific understanding of disease. The relative importance of these three pathways varies from case to case, and often they interact strongly. More specifically, we argue here that in cases of therapeutic innovation where a new medical technology is involved the advance in medical practice is driven largely by the ability to develop and use effective medical artifacts and the interactive sequence among these interdependent pathways often starts with what is learned in practice and not in science. While we state this argument in general, we develop it in detail in a longitudinal and contextual case study of the emergence and evolution of a treatment for advanced heart failure based on an implantable device, the Left Ventricular Assist Device (LVAD). Our findings show that an essential aspect of the evolution of the LVAD therapy is collective and cumulative learning that requires experience that only can be gained through the actual use of LVADs. We discuss the theoretical and policy implications that follow from our understanding of how medical practice evolves for research on the evolution of medical practices and new medical technologies, and policies about the evaluation of rapidly moving medical practices and clinical research involved in their advancement.
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1. Introduction: three pathways to the advance of medical practice

This paper is concerned with the emergence and evolution of an important new medical practice: the treatment of heart failure with the use of a medical device, the Left Ventricular Assist Device or LVAD. These devices are implanted in the body to assist failing hearts in pumping. Early versions of LVADs began to be used to help heart failure patients in the late 1960s, and since that time approximately 12,000 LVADs have been implanted around the world. As one might expect, today's LVADs are very different from the early versions. They are much more effective in preserving life, less prone to malfunction, and are much easier for the patient to live with than the earlier versions. In addition, the implantation procedure has become simpler and more routine. The developments we elucidate here are interesting in their own right. But the LVAD story also tells a lot about how advances in medical practice emerge and evolve more generally.

For the past several years we have been working with a group of scholars studying the advance of practice in several different areas of medicine, progress in dealing with cancers and diseases of the eye as well as the heart, new pharmaceuticals as well as new devices and new medical procedures (e.g. Gelijns, 1991; Morlacchi, 2002a; Metcalfe et al., 2005; Mina et al., 2007; Nelson and Gelijns, 2010). Studies of a variety of advances in particular medical practices are important to enable us to understand more generally how therapeutic innovations that contribute to the improvement of clinical care and the health of individuals and populations come about, i.e. their diverse origins and the complex iterative processes involved in their advances.

We notice that an inadequate and simplified understanding of how medical practice advances remains widely held in some policy circles, parts of the biomedical community and in the public at large with several unfortunate consequences. The most common view[1] is that remarkable progress in medical practice that has been achieved over the last century is largely the result of scientific research that has transformed understanding of how the body works and the nature of diseases. Under this perspective, new

[1] Another simplified view but that currently is much less influential in the biomedical and healthcare field is the 'technological fix', i.e. cheap and quick technological solutions for social problems that usually create more problems than they solve. See Rosner (2004) and Sarewitz and Nelson (2008) for a discussion about the technological fix for its difference with true technological solutions to problems.

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knowledge won through research has illuminated the pathways to dramatically better modes of care and prevention, which could not have been identified and developed in a dimmer or less accurate scientific light. Although some scholars (e.g. Pickstone, 1992; Gelijns and Rosenberg, 1994; Lowy, 1994; Zerhouni, 2003; Rees, 2004; Schechter et al., 2004) have pointed out that postulating a linear progress from medical science to medical practice is not an accurate description of their complex interaction, others (e.g. Murphy and Topel, 2003) have played an important role in keeping this view very much alive and shaping research policy and funding of biomedical and healthcare research[2] with unfortunate consequences as a result. For instance, while basic biomedical research has been handsomely funded by government, other important activities like clinical and health service research have been largely neglected (Moses et al., 2005).[3]

In this paper we provide additional evidence that a single minded focus on advances in scientific understanding of disease as the source of advances in medical practice is incomplete at best, and in many cases misses most of what is going on. We propose that medical practice evolves as a result of progress along three different pathways. One indeed is advance in scientific understanding. But at least as or more important in many cases is the improvement in the ability to develop new medical technologies. And learning in practice has been an extremely important feature of many medical advances, including the one studied here. Of course the relative importance of these three influences varies from case to case, and often they interact strongly. While we state here this argument in general, we will develop it in detail in our case study of the emergence and evolution of LVAD.

We certainly do not deny the importance of deep scientific understanding for many of the important advances in medical practice that have been achieved. However, it is important to recognize that, while there are important exceptions, in most areas of medicine, what has been learned is much better characterized as the accumulation of relative small and local advances than as dramatic breakthroughs in understanding. And while improved scientific understanding often points broadly to potentially more effective ways of dealing with a disease, the light it casts generally is relatively broad and diffuse. Also, by focusing on scientific research aimed to illuminate the nature of disease, this perspective tends to repress the importance of the two other pathways to advances in medical practice we highlighted above: the development of technologies used in treatment or diagnosis, and learning in practice.

The design and development of new medical technologies,[4] including the LVAD which is the focus of this paper, often has been stimulated and enabled by the advance of broad technologies whose principal uses and support lie outside the realm of medicine.

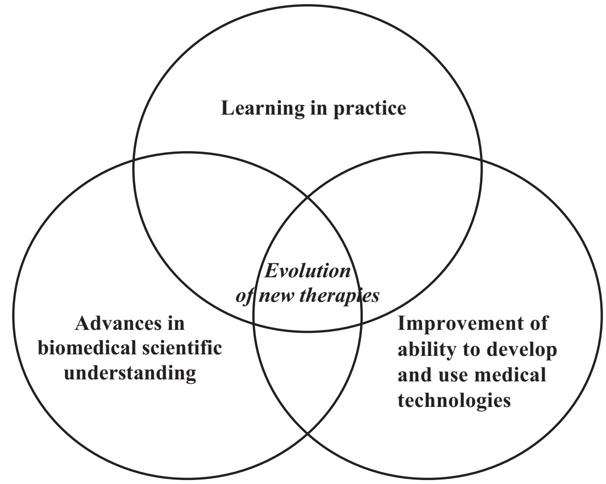

Fig. 1. Three co-evolving pathways.

Thus advances in electronics and computing, and the development of new materials, have had major effects on the kinds of medical technologies that could be developed. Moreover, in recent years the technologies associated with bioengineering have been important facilitators of the development of a variety of new medical artifacts, including drugs and devices (Bronzino, 2005). Often the development of new effective medical technologies made possible by these kinds of technological advances occurred independently of any better understanding of the disease they are used to treat (Gelijns and Rosenberg, 1994; Rees, 2002). For example, over the past 30 years great advances have been made in the treatment of cataracts. These have involved the use of new materials to create artificial lenses, new designs for lenses, and new modes of surgery. But these developments were not dependent to any significant extent on improvement in understanding of cataracts or the workings of the eye (Metcalfe et al., 2005). As we will show, LVAD is another case where the development of the device was not stimulated by or associated with any significant advance in medical understanding.

The strong focus on advances in scientific understanding also tends to be associated with neglect of the importance in many cases of learning gained in medical practice itself. As we will see, learning in practice has played an extremely important role in the development of the effective use of LVADs, similarly in the new treatment of cataracts mentioned above. In some cases there may be iteration between learning in practice and learning in research (Gershon, 1998; Rees, 2002; Lenfant, 2003; Williams, 2004). But in other cases, like that of LVAD, scientific research was not particularly important in guiding the development of improved practice. The use of new devices will often require the development of new procedures and other new organizational routines, i.e. new practices. As we will see, this was strongly the case in the LVAD experience. And where this is so, there may be significant interaction between what is learned in practice and the redesign of the artifact to take into account what has been learned and so as to facilitate more effective and better use.

More generally, the three pathways to progress in medical practice we have identified – advances in biomedical scientific understanding, the improvement of the ability to develop new medical technologies, and learning in practice (shown in Fig. 1 below) – tend to interact in a number of ways. We highlighted above the often interdependent and interactive improvement in devices and practices. But advances in either of these areas often provide the basis for new biomedical understanding, and may lead to a reorientation of research. In the LVAD case, experience in practice has led biomedical scientists to reconsider their old beliefs

[2] See Murphy and Topel (2003) for studies aimed at showing a direct causal relationship between biomedical basic research and health outcomes. These research efforts were promoted in the last ten years by advocacy organizations such as the Lasker Foundation to lobby the US Congress to increase its NIH budget (e.g. Lasker Foundation (2000) *Exceptional Returns*). Similar exercises were undertaken also in Australia and Europe (e.g. UK Evaluation Forum (2006) and European Science Foundation (2005)). See Buxton et al. (2008) for a critical review of these studies.

[3] It is relevant here to point out that the overall funding and federal spending of human health research nearly doubled between 1994 and 2003 with an expansion of funding of biomedical scientific research, and since early 1980s the total financing of biomedical research exceed that of engineering and the physical science. Moreover, translational research – the application of emerging scientific knowledge to new therapeutic avenues – and health service research – for instance the evaluation of the clinical and economic value of new technologies – are much less well funded than that of biologically based disciplines (Moses et al., 2005).

[4] Here technology is understood as the bundle of devices – tools, machines and artifacts or 'hardware' – and procedures – techniques and methods or 'software' – for doing something useful.

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