

Nanotechnology and Health Policy

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Introduction: Nanomedicine and Its Context

Nanomedicine, the application of nanotechnology to medicine, holds enormous potential to improve not just quality and timeliness of health care but to enable entirely new forms of diagnosis and treatment. It is often depicted as revolution compared to current medicine. While in terms of capabilities this will likely be true, as a technology it will develop over a span of time together (and based on) other fields.

Technology interacts with its organizational, social and political context and vice versa. Introduction of new technology hinges on the right preconditions; even a useful technology will not be adopted if it cannot fit into the organization. At the same time technology can enable new forms of organization, and the desire to use a new technology fully can force organizational restructuring to fit it.

Studying Nanomedicine Using Current Trends

Current trends towards information medicine and biotechnological medicine provide relevant data for the societal introduction of advanced technology into the health care system.

The emergence of well-informed patients that demand to be treated as customers rather than subordinate clients. This trend is enabled by the spread of information technology.

The new pharmacology is blurring the lines between palliative, curative, preventative and enhancing medicine. As patients are becoming more demanding they demand health and not just cures, and will also be aware of new treatment and seek them. This is supported by a changing view of health from a normative normalization towards health as a volitional state.

Regulation has hard to keep up with technological change, especially changes that go beyond current categories. This creates an uncertain climate for organizations and companies.

Monopolies of diagnosis and treatment are destabilized by the appearance of cheap diagnostic sensors and decision support tools that are increasingly available to lay-people, and increasing international and national competition between health care organizations.

Decentralization of information enabled health-care. Many expect that in the future the home will be the primary place for health-care delivery thanks to sensors, telemedicine, smart implants etc.

Fast technological change is putting many health care systems under organizational strain due to the need for education, the need to form transdisciplinary health care teams to deal with the many aspects of treatment, the expense of acquiring new technological systems, increased competition and regulatory uncertainty.

Systems Analysis of Feedback Effects Within Technology and Health Care

The current trends can be analyzed as a system of feedback interactions. Certain trends act as enablers, allowing other trends to develop. Other interactions are more direct positive or negative feedback effects.

Strong feedback loops exist between self-directing patients, a volitional health view and enhancing medicine. There is also a feedback loop between decentralized and competitive medicine. Technological change enables this process but does not drive it directly; rather it acts as a gate that increases the gain of feedback.

Organizational and regulatory strain are fueled by these feedback loops. In turn, they slow the development and deployment of new technologies as well as strive to retain traditional modes of organization and regulation. However, since their inhibition does not affect the main feedback loops or the general push towards advanced technology their effect is merely to increase the discrepancy between desire and reality.

The Effect of Nanotechnology

The main effect of nanotechnology on this model is to further amplify the enabling effects of technology by increasing the range and capability while decreasing the cost of many devices and systems.

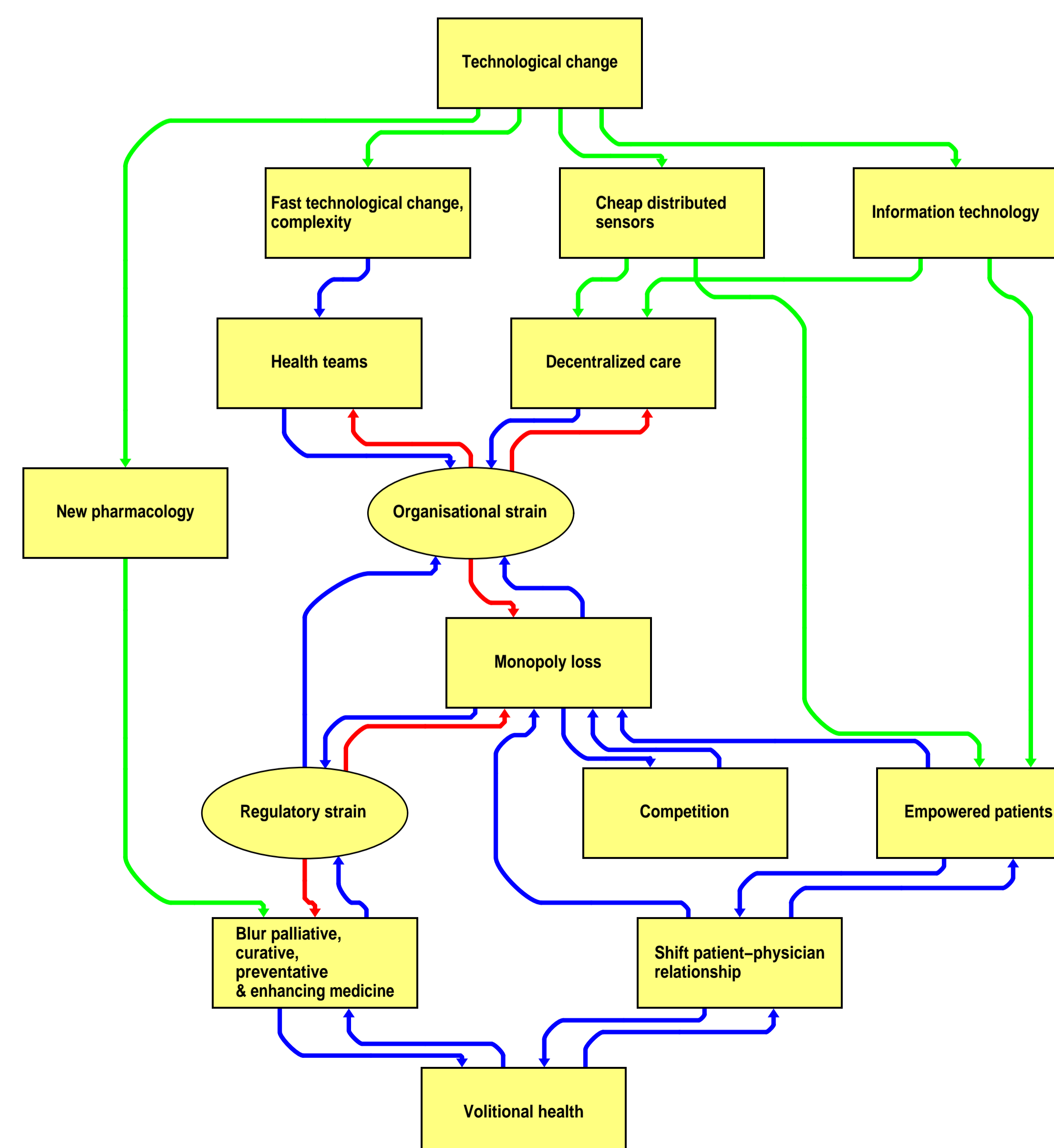
Nanotechnology will appear after information- and biotechnological medicine has been on stage for some time, implying that the state of feedback will be more strongly set by these than by nanomedicine.

Shortened Product Life-Cycle

Nanotechnology is likely to lead to shortened product life cycles. This is in turn likely to lead to lower prices and more competition in other areas than basic function (compare the cellular phone industry).

If regulation lags behind or the approval procedure remains slow consumer pull will remain unmet, creating a situation of black markets and faster development of nanomedicine in less slowed areas.

Nanotechnology enables higher degrees of individualized treatment in medicine; while pharmacogenomics enables finding the right drug for the right person in the right dose, nanotechnology enables manufacturing the right drug even if it is highly individual.



Competency Challenges

Short product life-cycles and transdisciplinary systems in fast development requires adequate training for both health care professionals and corporate personnel.

The need for broad competency may be hard to meet for many companies. Nanotechnological competency challenges will incur higher costs than traditional biotechnology and pharmaceutical companies. They will likely necessitate partnerships and cross licensing between companies in strategic alliances. Partnerships may develop not just between specialized companies but between nanomedical companies and health care organizations. These costs may act as a threshold limiting startups and benefitting big, diversified companies.

Regulation Problems

The competency challenge is also felt in regulation. Lack of regulation or uncertain regulation discourages investment. Current issues of how to regulate tissue engineering show the problems of technologies that cross regulatory boundaries; nanotechnology is likely to be seriously affected. At the same time the development of regenerative medicine may act as a path-breaker for a more flexible regulatory system for medical applications in the borderland between devices, drugs and transplants, perhaps based on function rather than means.

New technology is often assumed to require new regulations, which often leads to overly rigid or irrelevant regulations. It might be more profitable to develop an evolutionary regulatory system that develops in pace with the technology. Developing a climate of self-regulation by creating suitable incentives may also reduce the regulatory stresses and information overload.

Enhancing Medicine

More and more conditions that are not illnesses in the traditional sense are becoming treatable. As medical technology advances beyond "lifestyle medicine" treatments will increasingly become possible that enhance or change human functions beyond current levels. This is posing a strong regulatory challenge in many jurisdictions and will be a controversial ethical and political debate. At the same time the field is a huge potential market that remains to be exploited.

There is a need for the nanomedical community to face the issues surrounding enhancing medicine in order to avoid both ill-conceived ex ante regulations that block research but do not block misuse, and avoid negative public reaction by ignoring value issues (as has happened in the biotechnology sector).

Nanomedicine and Health Policy

Factors influencing how earlier technologies are applied will be crucial for the introduction of nanomedicine. If regulational and organizational strain due to these become too large application and investment in nanomedicine will be slowed. Hence it is in the interest of the nanomedical community to engage in the current issues of decentralized information medicine, enhancement medicine, new forms of medical organization and the changes of treatment monopolies.

Policymakers can benefit by using the nanotechnological community as a source of foresight and perspective. It is important to avoid premature categorization of products and treatments. Researchers have an incentive to engage the public and policymakers in debate about their field, in order to defuse potential conflicts such as the stem-cell issue. Here patient organizations may play an important motivating and mediating role.

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