SAFETY BY DESIGN

On the complexity of medical devices and systems

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How does one design something that is complex? Or something that is simple? Why should one try to reduce or increase complexity? What is complexity? There are a large number of different uses of the word, including many in mathematics and physics. Most of these are not useful in attempting to fit the word to the problems of the design of systems and devices for medicine. In this paper the concept has been defined to apply to health care, which has led to some conclusions about the future development of medical systems and devices.

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''Everything is simpler than you think and at the same time more complex than you imagine.'' Johann Wolfgang von Goethe

THE PROBLEM OF COMPLEXITY

Complexity has been held responsible for emergent (unexpected, surprising) behavior of medical devices and systems. How does one design something that is complex? Or, for that matter, something that is simple? Why should we try to reduce or increase complexity? Exactly what do we mean by complexity? I am not the first to ask these questions: Standish[1] says: ''*In the last 15 years, the study of complex systems has emerged as a recognized field in its own right, although a good definition of what a complex system actually is has eluded formulation*''.

WHAT IS COMPLEXITY?

The *ISCID Encyclopedia of Science and Philosophy*[2] offers eight formal definitions, and begins its discourse with:

''***Complexity** is one of those terms for which it is difficult to give a precise definition. Intuitively, it is thought of as a property or feature that implies the opposite of **simplicity**. Complexity is often used to describe single systems made of multiple interacting parts. However, complexity descriptions can be used for a large variety of applications*.''

A list of names, definitions and applications is shown in Appendix 1.

Which, if any, of these has relevance to the design of medical devices and systems? I prefer to define a new type of complexity and restate it as:

''*User complexity is a measure of both the **skill** required to use a device correctly and safely, and of the **work** required for a user to use it in that way*.''

In other words ''complexity'' is a perceived characteristic of a device or a system, and not necessarily related to the number of components or their interconnectivity. For example, my right arm is exceedingly complex for an anatomist; its correct use to accomplish almost any goal is exceedingly simple and spontaneous for its owner.

In medical systems, perceived complexity depends on who is doing the perceiving. This, in turn, gives rise to a need for a family of application complexities. I call these ''user-complexity'', ''engineer-complexity'', and ''technician-complexity''. There may therefore be devices and systems that are easy to use, difficult to design, and almost impossible to maintain. The perceived complexity would depend on whom you asked.

A properly designed medical device should be (as a design goal) one that any user de novo knows what it is for and be able to use it for that purpose without further instruction. If such a device existed it would be unimprovably simple; its user-complexity on a scale from 0 to 1 would be close to 0.

For a device to have such simplicity, its internal workings must defend against an almost infinite number of possible misuses by a user or failures of a component. From the view of the design engineer and the maintenance technician, its complexity would be very close to 1.

User-complexity

One can imagine that the user-complexity of a machine is related to the number of immediately discriminable input and output events that can occur, and the ease with which the inputs and the outputs can be immediately identified. If the identification of every input and every output is instant and accurate, then the user-complexity of the device is as close to 0 as it can be, short of complete automation.

Engineer-complexity

In an earlier day the measure of this kind of complexity would have been the number of parts and their interconnections. Today the concept of parts is almost meaningless; a chip is a part but its graphic representation is of an enormous number of identical units permanently fixed in a matrix of solid material. Complexity arises from the (approximate) fact that each of the identical units can be addressed and commanded to do something to each of the others. The programmatic logic required for the invisible (to the user) complexity generally will be highly complex. In general, as user-complexity diminishes, engineer-complexity increases.

Technician-complexity

Fault diagnosis can be a highly complex process because the effects of one or more of many enormous possible faults may be completely unpredictable. Repair, on the other hand, is not

complex at all. It is easier than for a pocket watch of a century ago: an identical chip replaces the defective one. A modestly skilled technician can do it in a few moments. The added complexity of inherent self-diagnosis will diminish still further the complexity perceived by the technician. As technician-complexity diminishes, engineer-complexity increases.

CAN THE COMPLEXITY OF A MACHINE BE QUANTIFIED?

A machine in which a chip is installed may appear to be a very simple device to be directed by a human user using some simple parts (such as controls and displays) to execute some simple electrical switching procedures on some other simple parts (such as sensors and valves).

Is the system simple or complex? Complexity is a multidimensional quantity composed of the number and diversity of intended functions, necessary user skills, inherent difficulty of use, nature of input and output, probability of user error, probability of component failure, predictability of outputs, cost of failure, and ease of maintenance and repair. ''How complex is this system?'' is almost unanswerable and probably of little value. A system may be internally complex but simple to use. A machine of relatively few parts, simply interconnected, may be complex for the user if the design offers no guidance on its face as to what must be done to get the machine to do what it is supposed to do. Whether a machine is simple or complex, and how much of either, depends on whom you ask. On the other hand one could, of course, sum the three vectors of design, use, and maintenance to yield a single index of complexity. That any such measure would be useful is doubtful.

Why does the problem of complex medical system design continue to exist? The Institute of Medicine report[3] identifies ''key elements in an approach to complex adaptive system design'' such as: ''*Use biological metaphors to guide thinking. Create conditions in which the system can evolve naturally over time. Provide simple rules and minimum specifications. Set forth a good enough vision and create a wide space for natural creativity to emerge from local actions within the system*.''

Why do we need to do all this? We must challenge some of the assumptions that are sometimes explicit—more often implicit—in the current view of complex systems. For example, we are told by the chaos theorists that the Earth is exceedingly complex and that a butterfly flapping its wings in Brazil may give rise to a storm that will turn off the lights in Rockville. In reality the Earth is very complex in that it is unknowable in its entirety. AND it is all very simple because the complexity is invisible to the observer. (More to the point, the disturbance created by the butterfly's flapping of its wings gets absorbed in the first meter of separation by a virtual infinity of miniscule random events.)

Hospitals are, in fact, organized in pretty much the way that the Institute of Medicine[3] proposes. There is deviant behavior calculated to circumvent excessively constraining rules. Such behavior arises from necessity—workers must circumvent rules if the work is to be done. When organized labor wishes to strike without striking, the rule is ''work to rule''. If hospitals worked precisely to rule, their functions would grind to a halt.

Despite this repeatedly demonstrated truth, managers persist in designing systems and writing operating rules that are never followed precisely. I propose that virtually all of the difficulties we encounter in our systems arise from a failure imaginatively to consider in the design process the human propensity to err. The undesired unpredictability of the human components of healthcare systems is largely with respect to when errors will occur. What error can occur is often relatively predictable in that it comes from a bounded, and not always very large, set of possibilities. In brief, a person who errs can do nothing that is not present to be done. One must look at the fine detail in order to weed out those affordances that lead to unsafe behavior. Complexity has little to do with it.

Errors of intention—''mistakes'' that can lead to an erroneous diagnosis or the choice of an incorrect procedure—are more difficult to design out. Here the range is very large and indeterminate. These, however, are errors that will not be forestalled by answers to all the worrying questions about complexity. They arise from mechanisms that are not within the scope of system designers, unless the concept of system design is expanded indefinitely to take account of the possibly infinite number of ways in which the human central nervous system can go awry.

Both user-complexity and engineer-complexity exist in any sufficiently large systems no matter how simple and mechanical and non-adaptive they may be. They become adaptive by virtue of their human components.

Goethe was right. I interpret his thought for the modern problem to mean:

> ''For any medical device or system, internal complexity must increase as surface complexity decreases. As less and less skill, judgment, and intelligence are required at the user-system interface of a device or system, more and more complexity is required behind the interface to provide the operational intelligence required by the goals.''

In the future the engineer-complexity of devices and systems will grow, merely because it can. The drift toward increasing surface simplicity is apparently irreversible for that reason. The human component of medical systems will find fewer and fewer demands for creative solutions of problems since the solutions, and the knowledge base on which solutions rest, will be embedded in the inexhaustible memories and interconnectivity of the machines.

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REFERENCES

1 **Standish RK**. On complexity and emergence. *Complexity International*, 2001, Volume 09. http://www.complexity.org.au/vol09/standi09.
2 **International Society of Complexity, Information and Design (ISCID)**. *ISCID Encyclopedia of Science and Philosophy*. http://www.iscid.org/encyclopedia/Complexity.
3 **Institute of Medicine**. *Crossing the quality chasm. A new health system for the 21st Century*. Washington, DC: National Academy Press, 2001, Appendix B.

APPENDIX 1 DEFINITIONS OF COMPLEXITY (EACH TO HIS OWN)

Computational complexity is a measure of the time and space requirements to perform a certain computational function.

Time complexity is the length of time it takes to find a solution or complete a process.

Space complexity is the amount of physical storage required for a system to perform a certain operation.

Kolmogorov (algorithmic) complexity is the length of the shortest program run on a universal Turing machine capable of performing a certain function or providing a certain output.

Connectivity complexity is the number of relations/interconnections between the components of a given system. The greater the extent of interconnections between

components of a system, the more difficult it is to decompose the system without changing its behavior.

Descriptive/interpretative complexity is the complexity of a system that involves both a description (eg DNA) and a realization of the description (eg proteins in the cell). This complexity is measured as the total complexity of encoding the realization into a descriptive code and decoding it back into a realization of that code.

Functional complexity is the sum of the complexity of the individual functions that can be realized by a single system.