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Knowing What We Know About Health Care

Remarks to The Cleveland Clinic Medical Innovation Summit

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It's certainly a privilege for me to be a part of the Cleveland Clinic's Medical Innovation Summit ... and I'm very grateful to Dr. Cosgrove for the invitation to speak.

The Cleveland Clinic is nothing short of a national treasure ... as well as a godsend to patients ... and it behooves us to ask: Why?

Certainly, the Clinic's track record of innovation is part of the explanation. It was the site of the first human-to-human blood transfusion ... the first coronary artery bypass procedure ... and many other inventions, now flowing at the rate of nearly 200 per year. The assembly of talent at the Cleveland Clinic is another part of the explanation ... hundreds of the world's top clinical and research physicians in almost every area of specialty.

But I would argue that those things are just manifestations of the Cleveland Clinic's real source of greatness. The Cleveland Clinic is, quite simply, one of the world's largest concentrations of knowledge about human health.

It is the different strands of knowledge ... coming together ... that have led to so much innovation around the Cleveland Clinic. It is the critical mass of knowledge ... on the part of the faculty ... that attracts yet more such talent. And it's the impact of knowledge ... on the quality of care ... that gives patients such a high level of confidence in this institution.

To put it mildly, patient care in general does not always live up to the standards of the Cleveland Clinic ... perhaps not even, in certain cases, at the Cleveland Clinic itself.

Very often, that's because knowledge depends on two, less glamorous cousins that go by the names of "data" and "information." When health-care data and information are not available ... or when they are poorly organized and understood ... then health-care knowledge is greatly diminished.

It happens in isolated geographies, without a critical mass of medical expertise ... in emergencies far from the family doctor and her files ... and, let's face it, all too often throughout the health-care system. The necessary information and data simply are not available – and so the full knowledge of "what can be done" ... is not brought to bear.

There used to be some good excuses for this poor diffusion of information ... and for the time lags in obtaining medical data. Chief among them were the dependence on paper records ... and the tyranny of distance, against which the postal service and even the fax machine were poor remedies ... along with the sheer institutional complexity of the health-care system.

But frankly, those excuses are wearing thin. In fact – post-PC, post-Internet, and post-wireless technology ... those excuses are getting rather embarrassing.

Data on patient outcomes is being gathered in many forms – for example by drug companies carrying out large clinical trials ... by health insurers amassing claims data on the lives they cover ... by doctors building files on patients ... and by regulators collecting reports of adverse events.

As a result of such data collection – which has been going on for decades in some cases – along with exponential increases in computing and telecommunications capacity – we now have the theoretical ability to know more things, more quickly, about more patients, at a greater level of detail, than ever before.

And yet we're not translating this ability from theory into practice. At best, some of us are seeing pieces of the whole, but the totality of insights that could emerge from this treasure chest of information ... is being denied to everyone.

The inescapable conclusion is rather painful to admit: We do not know what we know about health care!

There are some signs of progress. With bipartisan support, for example, the new National Coordinator for Health Information Technology – or health IT, to use the shorthand – has helped to build urgency ... and to drive the adoption of standards. The Centers for Medicare and Medicaid Services have been quite creative in encouraging and testing the use of electronic health records among the people they serve.

At the regional, level there are successes in building health-data networks – notably the Indiana Health Information Exchange in Lilly's hometown.

And many private health-care businesses ... such as the Cleveland Clinic with "Doctor-Connect" and other e-health initiatives ... are moving forward within their own ranks.

However, I'm convinced that we are still selling short the benefits of a true "Information Revolution" in health care ... and, as a result, we are moving too slowly to realize those benefits.

Bringing the Information Revolution to health care is not a panacea that can take the place of much broader reforms. A wired health-care system that otherwise fails to secure the requirements of innovation and quality ... will be like an attractive façade that conceals a decaying structure.

Conversely, I do not believe that we can truly cure any of the maladies facing the health-care sector ... without an all-out effort to close the knowledge gaps and knowledge lags. Let me offer some examples dealing with the cost and quality of health care. Together with access issues, these form the troika of problems typically associated with our current system.

Example Number One: The challenge of paying for health care clearly has reached crisis proportions in most of the developed world. Yet, experts have identified enough waste in the current system to make up for some fairly significant increases in the kinds of health-care spending that are truly valuable and productive.

The waste falls into at least four categories. There's administrative overhead in health care – estimated at a third of all U.S. health-care expenditures. There's the cost of unnecessary care – treatments that will contribute little or nothing to the wellbeing of the patients receiving them. There's duplicative care – patients undergoing two or three diagnostic tests at the behest of various doctors, for example, when one test would do. And there's poorly targeted care – such as the hit-or-miss prescribing of medicines that do not match patients' genetic profiles or their progression in a disease.

These four areas of wasted spending – even using conservative estimates based on a range of studies – total in the tens of billions of dollars each year. And in every case, the key to improvement is knowledge – both streamlining the acquisition of information ... and getting it to the right place at the right time to inform medical decisions and help patients.

A second example is the challenge of drug safety. The use of prescription medicines always will be a matter of balancing benefits and risks. Frankly, that's the first and most basic insight that needs to be understood by health-care consumers ... not to mention the news media and politicians. Fortunately, systems are now within our grasp to much more quickly identify both the true benefits and the full extent of risks associated with medicines in widespread use.

Traditional, Phase IV, post-marketing drug trials will of course continue – to test new hypotheses about medicines. Indeed, it's the intent of the new FDA reform legislation to promote much wider involvement of health plans, academic medical centers and other sponsors of Phase IV research.

A well-functioning health IT system, however, could serve not only to frame hypotheses for such clinical research ... but also to turn much of day-to-day medical practice into the practical equivalent of Phase IV trials. Such a system could feed insights to doctors, regulators, and drug manufacturers more quickly, cost- effectively, and at a higher level of confidence than is currently the case.

By way of example: A professor at Harvard Medical School recently determined that networked data on 100 million patients ... something that's certainly feasible with current technology ... could have produced a statistically meaningful "signal" of cardiovascular risk less than three months after Vioxx went on the market.

In the same way, it's within our reach to obtain evidence much more quickly about the unexpected benefits of medicines in practice. This could lead to faster approval of new indications ... and stronger insights on what types of patients truly will benefit from a particular course of treatment.

My last example is perhaps the most straight-forward. The U.S., and many other nations, worry about the growing pandemics of chronic diseases – among them diabetes and its adjuncts of obesity and vascular complications.

Absent a cure, it's not in our power to stop the diabetes pandemic completely. But I submit to you that it's wholly within our power to keep a significant number of patients from developing full-blown diabetes ... and also to slow down the progression of the disease in many other patients – which will bring a great deal of human and financial benefit.

In the U.S., studies confirm that about one in three people with diabetes has not even been diagnosed with the disease. And a Duke University research project found that among patients newly diagnosed with diabetes, fully 21 percent did not have an HbA(1c) test within the first year ... 45 percent did not have an eye exam to screen for retinopathy ... and more than a third made no changes in their diets. Indeed, they received no medical treatment whatsoever for diabetes.

Clearly, this is one of those areas in which health IT is no panacea. It's not simply for want of an Internet connection ... that large numbers of patients fail to get quality health care. But receiving adequate and timely health information is bound up ... across the board ... with diagnosis, treatment, and patient compliance.

A study supported by the Robert Wood Johnson Foundation projected that IT- enabled disease management in diabetes ... could boost adherence to standards of care from about 50 percent to as high as 80 percent.

Even if the real improvement is less than half that good, that's still tens of thousands of patients who would otherwise develop the serious complications of unchecked diabetes.

Now in talking about how to move from potential to reality in health IT, it's important to distinguish two broad areas.

There's the effort to develop what are usually called "health-information exchanges" – which are protocols and systems that permit existing data to be shared between the diverse players in the health-care system.

And then there is the pursuit of what are variously called "Personal Health Records," "Electronic Health Records" or "Electronic Medical Records." I'll call them "EMRs" for short. These are rich, patient-specific repositories of clinical information on diagnoses, treatments, and outcomes ... which ultimately could include genetic information as well – as the basis for tailoring therapies to particular patient profiles.

Today, already, health-information exchanges in parts of the U.S. are supporting large-scale pilot programs in disease management, electronic prescribing, transmission of test results, and the analysis of health-claims data, for example. Large-scale implementation of EMRs, on the other hand, is proving a more elusive goal, for reasons I'll discuss in a moment.

To fully realize an Information Revolution in health care, we need both – secure, well-integrated data systems ... but also the robust content of EMRs.

To understand the importance of EMRs, just consider the pharmacovigilance challenge I described earlier. It would be possible to implement a system based entirely on health-claims data submitted to private insurers and to Medicare. But such a system would be a poor stand-in for a system that also included the actual health records of large numbers of patients. The limitations of diagnostic coding ... as opposed to true clinical record-keeping ... are well known to all of you.

Without descending too deep into the weeds, let me argue that the keys to achieving large-scale health IT – of both varieties – can be grouped into three categories: infrastructure, policy ... and mindset.

Of those, progress on the infrastructure may be the "easiest" to obtain – and I use the word "easiest" with all due sobriety. With regard to information exchanges, there is no need to reinvent the wheel ... or the Internet in this case.

The nascent National Health Information Network – endorsed by the federal government's health IT coordinator – is based on a "network of networks" model ... in which common technical protocols permit the inter-connection of regional systems. We cannot expect the market to produce agreement on such standards ... so it's an appropriate role of government to establish them.

At the regional level, in turn, what seems to be happening is that successful pilot systems are at the same time growing from urban into rural areas ... while being replicated in parts of the country that are just getting started.

That's happening here in Cleveland, as I understand it. Northeast Ohio's regional health-information organization, the so-called "NEO-RHIO," is seeking bids from more established RHIOs to import successful technology.

As these systems build out, they provide what amounts to a "commons" in which more specific health IT initiatives can be carried out. Using the Indiana exchange, for example – as well as data from the Partners Healthcare System in Boston – Lilly is working with J&J and Pfizer on a project to understand how we can find safety signals in large clinical databases.

I'm optimistic that these three layers of activity ... national standard-setting, regional expansion, and public-private experimentation ... soon will create a critical mass of basic infrastructure.

With regard to policy, the real urgency has to do with spurring EMR proliferation – and the crucial players that need to be brought along are patients and doctors.

A large survey commissioned recently by the Markle Foundation found that two out of three Americans would like to have electronic access to their own medical records ... and three out of four are willing to share their personal medical information for public health purposes. Those results really suggest that resistance to health IT is perhaps overstated.

The survey found that public concerns center on the protection of privacy ... not surprisingly ... and a strong desire to keep their medical information out of the hands of marketers. Those are legitimate concerns, to say the least, and the federal government should act on them.

Step One is to help educate Americans about the tremendous potential of EMRs to improve the quality of care. Just as importantly, clear privacy standards are needed on the secondary uses of medical records – even more so, when genetic profiles are part of the mix.

Lilly aims to help lead in this area. For example, we are in the process of convening a roundtable on privacy ... and other ethical issues involved in EMRs and the rise of personalized medicine. But the best way to lead is by example, so I am proud that earlier this year, Lilly became one of the first two companies ... the other is IBM ... to adopt an official policy that our employees' genetic information can never be used to discriminate against them in employment or benefits decisions.

Of course, once privacy standards and laws are brought up-to-date, then there must be strict enforcement ... to build public trust.

Changes in mindset are required of health-care providers as well – especially doctors. In particular, it's a matter of creating incentives for the application of EMRs in medical practices. The up-front capital costs for EMR systems have come down, but incentive payments by Medicare still could make the difference.

Rather than paying outright subsidies for EMR use, it makes sense to provide incentive payments to doctors for improving patient outcomes and reducing costs. To the extent that EMRs help to achieve those goals – and they do – then more doctors will be inclined to proceed with them ... and their efforts will be more likely to stick.

On the regulatory front, the time is ripe for the FDA, industry, the medical community, and patient groups to

collaborate on a reform of our nation's pharmacovigilance system along the lines I described earlier ... to speed up the recognition of safety signals ... and to understand the true efficacy of medicines on the market.

In the end – even with a workable infrastructure and the right policy decisions in place – a true Information Revolution in health care will require a new mindset from all of us.

For health-care providers, that means embracing EMRs not as a bureaucratic add-on to an otherwise unchanged practice ... but rather, as a key component of broader quality improvements. In particular, if electronic patient data is going to have a truly game-changing impact on health care innovation and quality, then it will be very important for doctors to keep better records on the outcomes of therapy in individual patients ... to code results as well as diagnoses and treatments.

For businesses that generate health data and new knowledge, it's time to learn the benefits of openness. We need to open our minds to the notion that electronic outcomes data – once the privacy of individual patients is protected – represent a legitimate “commons” ... a resource to which access should in most cases be widespread and easy.

That's not to ignore the fact that great effort and expense goes into collecting many types of health information. Certainly at Lilly, we spend hundreds of millions of dollars every year on clinical trials. But the key insight in our situation ... and I think it applies quite broadly ... is that unlike most other assets, health information actually becomes more valuable the more it is used, studied, and applied. It does not depreciate.

Three years ago, Lilly became the first pharmaceutical company to publicly disclose the results of all of our clinical trials – on the Internet. Far from harming our business in some way, I'm convinced that the increased transparency helped to improve our partnerships with researchers and to boost the confidence of doctors and patients who use our products.

You still may be wondering why the CEO of a pharmaceutical company is talking about the future of health information. I cannot speak for the entire industry, but I can tell you why it matters to Lilly.

We've been feeling great pressures from our environment – pressures on pricing and market access along with reduced tolerance for risk in the use of our products. We've chosen not simply to lament this state of affairs ... but rather to change our business accordingly.

Lilly's vision is one in which individual patient outcomes are the measure of our success. We believe that is the best way to increase the value proposition of pharmaceuticals in the eyes of all of our customers – doctors, payers, and patients alike.

Improving individual outcomes means tailoring our therapies to the patient populations in which they clearly work ... and in which their side effects are in reasonable proportion to their benefits.

It also means having courage to measure our products against other treatments ... and accepting the results as an appropriate basis for how our products are used and priced. We're doing just that ... as those of you who follow cardiology may know ... in our trial of prasugrel on a head-to-head basis against Plavix.

It means learning to communicate with patients – sometimes directly and sometimes through doctors or payers – not primarily to sell them our products ... but rather to educate them on how lifestyle factors, genetic characteristics, co-morbidities, and adherence to larger treatment plans ... all contribute to health outcomes.

That's a tall order – but it makes us excited about the promise of Lilly and our industry.

Notice that in every respect, our vision is much more likely to become reality if the Information Revolution finally reaches health care ...

- if we can quickly mine not only our own clinical trials but all others – for clues about the tailoring of our molecules ...
- if we can put rapid feedback loops in place – from post-marketing surveillance back into R&D ...
- if we can point to hard evidence for the economic as well as therapeutic value of our products ...
- and if patients are empowered with information about their own medical histories ... and their treatment options.

Knowing what we know about health care ... Lilly expects to be better off – to the extent that doctors, payers, and patients are better off as well.

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