Conversations with Medical Informatics Pioneers:
An Oral History Collection

Everything Electronic Medical Records: Systems, Standards and Studies

2004 Interview of Clem McDonald

Interviewers:

Joan S. Ash & Dean F. Sittig

Editors:

Rebecca M. Goodwin, Joan S. Ash & Dean F. Sittig

NIH U.S. National Library of Medicine

Everything Electronic Medical Records: Systems, Standards and Studies

2004 Interview of Clem McDonald

Conversations with Medical Informatics Pioneers:

An Oral History Collection

Interviewers:

Joan S. Ash & Dean F. Sittig

Editors:

Rebecca M. Goodwin, Joan S. Ash & Dean F. Sittig

Published by the U.S. National Library of Medicine, April 7, 2017.

Copyright Information

Government information at NLM Web sites is in the public domain. Public domain information may be freely distributed and copied, but it is requested that in any subsequent use the National Library of Medicine (NLM) be given appropriate acknowledgement.

Suggested citation:

McDonald CJ. "Everything Electronic Medical Records: Systems, Standards and Studies," *Conversations with Medical Informatics Pioneers: an oral history collection*. Ash JS, Sittig DF, interviewers. Goodwin RM, Ash JS, Sittig DF, editors. Bethesda: U.S. National Library of Medicine (NLM); 2015. Available from: http://lhncbc.nlm.nih.gov/project/medical-informatics-pioneers

Photographs:

In using NLM Web sites, you may encounter documents, illustrations, photographs, or other information resources contributed or licensed by private individuals, companies, or organizations that may be protected by U.S. and foreign copyright laws. Transmission or reproduction of protected items beyond that allowed by fair use as defined in the copyright laws requires the written permission of the copyright owners. Specific NLM Web sites containing protected information provide additional notification of conditions associated with its use.

Content distributed via the NLM Conversations with Medical Informatics Pioneers Oral History Project may be subject to additional license and use restrictions applied by the depositor.

Oral History Interview with Clement J. McDonald

Editors: Rebecca M. Goodwin, Joan S. Ash, and Dean F. Sittig

Interviewers: Joan S. Ash and Dean F. Sittig

Managing Editor: Rebecca M. Goodwin

Copy Editing: Cindy Allen

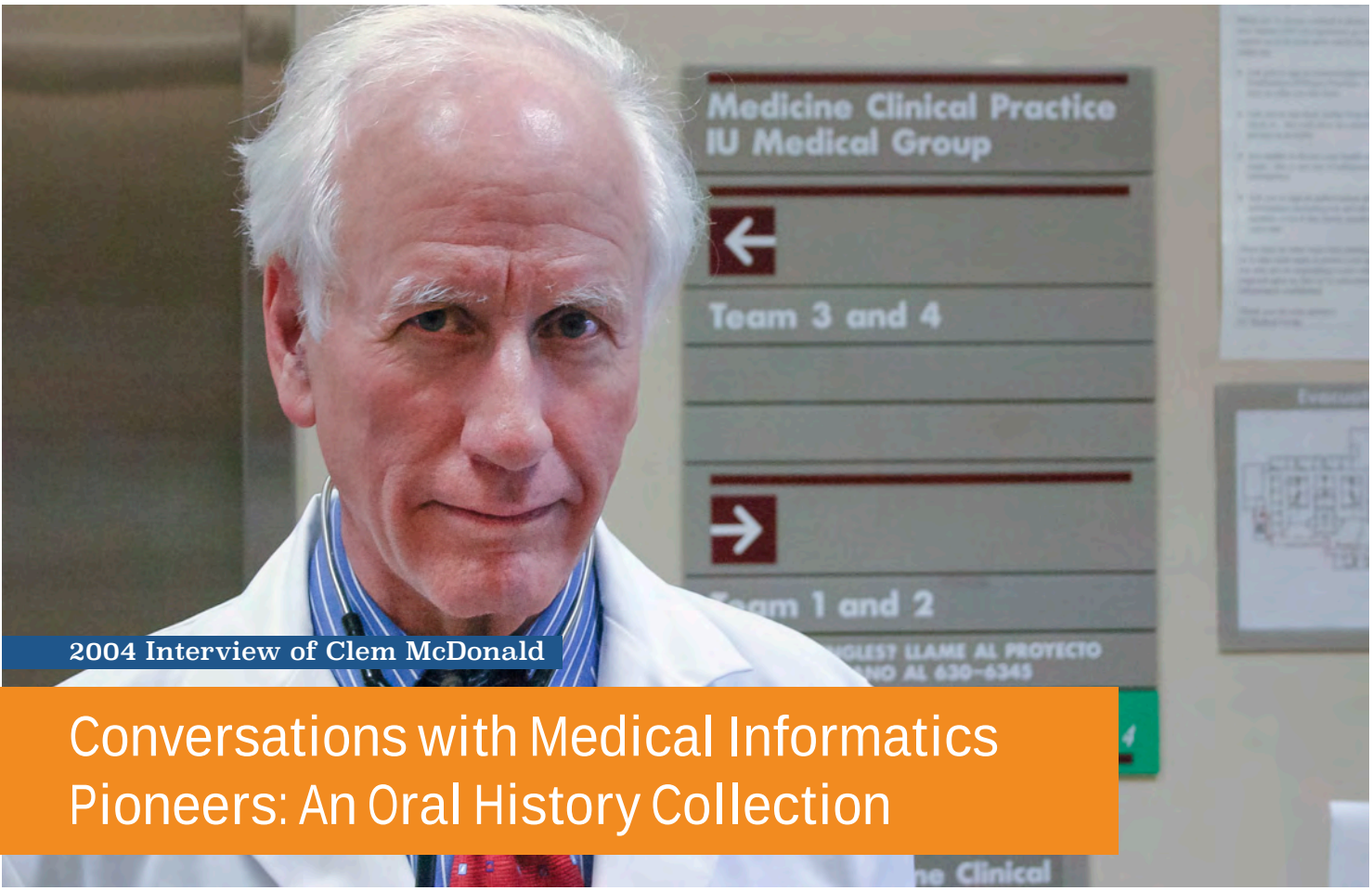
Design & Layout: Troy Hill, Bona Kim, John Harrington and Anne Altemus

Photo Editing: Troy Hill

Photo Captions: Clement J. McDonald, Rebecca Goodwin

Deeds of Gift: Rebecca Warlow, John Rees and Jeff Reznick

Contact: wwwnlm@nlm.nih.gov



2004 Interview of Clem McDonald

Conversations with Medical Informatics Pioneers: An Oral History Collection

Source: Personal collection of Clement J. McDonald.

Dr. McDonald in the clinic, August 2004.

Everything Electronic Medical Records: Systems, Standards and Studies

Dr. Clement J. McDonald is a pioneer in the development of electronic health record systems and health data standards.

INTERVIEWED BY
JOAN ASH & DEAN SITTIG

AUGUST 26-27, 2004
INDIANAPOLIS, IN

Clem McDonald, MD, is one of the pioneers of medical informatics.[1,2] In addition to his pioneering work in the use of clinical alerts and reminders,[3,4] he is one of the founders of the standards movement, including both Health Level Seven (HL7)[5–8] for messaging, and Logical Observation Identifiers Names and Codes (LOINC®).[9] Starting in 1972, he developed the Regenstrief Medical Record System (RMRS),[10] one of the very first electronic medical records system (EMR).[11–13]

In this conversation, he describes some of the most important rules he has learned for successful clinical information system development.

Dr. McDonald was a Distinguished Professor of Medicine and held the Sam Regenstrief Chair of Medical Informatics at the Indiana University School of Medicine at the time of this interview and is now emeritus. He was also Director of the Regenstrief Institute, where he developed the Indiana Network for Patient Care, which evolved into the first and

largest U.S. health information exchange (HIE) and a national model for HIEs in the U.S. In 1976, he published the first randomized trial of electronic medical records intervention in The New England Journal of Medicine.[4]

He proposed a design for the first clinical data exchange standard in 1984,[14] *which became ASTM 1238-88*[15] *and then the core of HL7's clinical reporting standard. In 1994, he initiated the development of LOINC —an identification system for clinical observations which has been adopted worldwide.*[9,16–19] *As of 2016, LOINC has been translated into 12 languages, and more than 44,000 people in 171 countries use LOINC to make bridges connecting their islands of health data. LOINC is mandated by regulation in the U.S. as the required code for almost all observations—including laboratory tests, survey instrument questions, and clinical findings. It has been adopted by most large laboratory vendors and laboratory instrument manufacturers. Dr. McDonald is also the co-author of the Unified Code for Units of Measure (UCUM) standard for units of measure.*[20–23]

He was the second President of the American Medical Informatics Association (AMIA) and a Regent for the American College of Physicians (ACP). He was the founding editor of MD Computing, and served as its editor from 1983-1989, when Warner Slack took the reins. Two years after this interview, he retired from the Regenstrief Institute and Indiana University to become the Director of the Lister Hill Center for Biomedical Communication at the U.S. National Library of Medicine at NIH in Bethesda, Maryland. Clem and his wife Barbara are proud parents of Clem III, Carolyn, and Christopher, and doting grandparents of five grandkids.

Source: Personal collection of Clement J. McDonald.

Clem McDonald, circa 1944.

JA *It is August 27, 2004. This is Joan Ash and Dean Sittig, interviewing Clem McDonald for the History of Medical Informatics Project. I've already warned you I would be asking you once again about your early days, where you were born and raised, your education, and how you reached informatics.*

CM Early, early days?

JA *Where were you born and raised? Let's start there.*

CM Okay, born in Chicago and raised in Oak Park and River Forest, the west side of Chicago, in a family of five kids. We lived in a three-story apartment building until I was 13. My mother got breast cancer when I was in sixth grade. She had surgery, and we were told she was cured but not what was wrong with her. Illnesses were always secrets in our immediate and extended family. A priest from a military boarding school gave a sales pitch during my seventh-grade year about his school, and I was sold—it was the place for me. But

Source: Personal collection of Clement J. McDonald.

Clem's mother, Margaret ("Babe"), sisters Betty and Peggy, and younger brothers Michael and Ray, circa 1951.

Mom just said no, absolutely no. I did not understand her unbending response because she usually listened to me and gave me a long leash. Her cancer seemed to be cured for a few years, but then she developed back pain, and we kids were told she had a slipped disc. In February, a few months after my 17th birthday, she died of breast cancer. That was a dark, painful period, and then I understood why she did not want me to go away to a boarding school for my high school years.

Source: Personal collection of Clement J. McDonald.

Clem (back) with his brothers and sisters (left to right), Ray, Peggy, Michael, and Betty, circa 1952.

I went to a local Catholic high school and then to Notre Dame. You were supposed to apply to many colleges. I only applied to Notre Dame. It was close, and that worked. I applied to two medical schools: the University of Illinois and University of Chicago, both within commuting distance: one subway ride to University of Illinois and two, with a transfer, to the University of Chicago. I was a bookish kid, and, from at least the middle of grammar school, had a reputation—I was supposed to be a scientist. University of Chicago had the bigger scientific reputation, but the researcher they assigned to interview me was the dullest, most dry human being with whom I have ever spent an hour. "If they're all like this, I don't want to be down here at all!" [laughter] Probably, in retrospect, he must have had some kind of disease, because he had these enormous long pauses between sentences, and sometimes, words. "Come on! Come on!" I was thinking, as I waited between each word. [laughter]

So I went to medical school at the University of Illinois. It was a fifth of the cost ($250 a semester), and it was closer. I lived at home for the first two years.

DS ***What year was that when you started medical school?***

CM 1961.

DS ***You seem to have a predilection for county hospitals. What was your first experience with a county hospital?***

CM When I was in fifth grade—nine years old in the fall of 1950. My parents were pretty strict, and you couldn't get out of school by just saying you were sick. You had to have a fever. We came home for lunch every day, about a half-mile walk each way. We had an hour to walk both ways and to eat lunch. One day, I started really feeling sick at lunch, and my mom let me stay home that afternoon. But the next morning, my dad took my temperature. It was normal, and he said, "You go to school." Walking home for lunch that day with my older sister Betty, I got pretty nauseated, then I fainted, smack down to the ground.

By evening, I was on a hard metal table in a very sterile-looking room, and my pediatrician was prepping me for a spinal tap.

By evening, I was on a hard metal table in a very sterile-looking room, and my pediatrician was prepping me for a spinal tap. I remember clearly the smell of antiseptic, and pain—first in the center of my back, and then shooting down my leg. "Please stop," I thought. From that experience, I thought spinal taps had to be painful, but as an intern at Boston City Hospital, I did tons of them, and if I placed a blister of Novocain just under the skin and kept the needle precisely in the mid-line, they were mostly painless. My pediatrician, whom we loved, never learned this trick. The spinal tap results said, "Polio!" Everyone was terrified of polio's contagion

so they had to put me in an isolation ward, and only Cook County Hospital—a huge, 1,500-bed, public hospital—had one. They quarantined my four siblings. The wait in the admitting area seemed like forever. Then, they put me on a gurney, rolled me down the hall with my mother alongside and my father close behind. They pushed me into a freight elevator-sized cage with iron open-air grillwork for its walls, ceiling, and entrance gate. The gate closed noisily (ka-chunk!) and with finality. My mother tried to stifle a sob on the other side of the gate but did not succeed. That made me think I had something really bad.

It was a 30-bed ward with just two patients: me and a two-year-old kid at the other end. I spilled the metal drinking water pitcher on me that first night. The bedding consisted of a sheet on the mattress and another sheet for a cover, no blanket. I shivered under the wet sheet. No one answered my call button.

One of my treatments was immersion in hot water once a day. They would lift me over the tub and drop me in the hot water. To me, it was scalding water torture and I was sure my skin would blister (it didn't). I dreaded that tub, but maybe it helped. Each day, a whole team of doctors would examine me, lift up my back-tied gown, listen to my breathing, and test my strength. I could not sit up without assistance.

I had only one visitor in my 10-day stay. Because she was a physician faculty member at the hospital, my Aunt Lyn was able to sneak in, but just once. What a joy. Life also improved after her visit—the water was never too hot. In early December, they sent me home for three months of bed rest. It was a cold and snowy December (−17 degrees Fahrenheit one day). Winter took itself seriously back then. My mother would bundle me up, put me in a sled, and pull me to the grocery store two blocks away so that I got some "fresh air." We would pass by 10-foot pyramids of snow plowed into the corners of the gas station. While I was home recuperating, I read the encyclopedia. I actually skipped monographs that were really boring. But I read all the scientific parts and the geography and the history. When the word got out that I read the whole encyclopedia, I got the reputation that I was definitely going to be a scientist.

While I was home recuperating, I read the encyclopedia.

Polio paralyzed my waist and some back muscles so I couldn't sit up, I couldn't bend up. I had to kind of roll over on my side to get up and out of bed, but

Source: Personal collection of Clement J. McDonald.

Uncle James McDonald, MD, and Aunt Lyn Kosar McDonald, MD, just married, and Clem, age 5, as ring bearer, circa 1945.

that passed after a month or two, so it wasn't a serious, dangerous case of polio.

I went to a parochial school where some of the nuns did not spare the rod. My fifth-grade nun was particularly tough and would not hesitate to slap me around if she caught me talking or joking with a kid next to me. But when I returned to school in the spring, she treated me like fragile porcelain. If I talked to the kid in the desk behind me during class, she would still get mad and shout, "Get up here!" But when I stood in front of her, she would wind up, but couldn't hit me [chuckles]. I mean, you could just see her turning red. She would finally yell, "You go sit down!"

Uncle Jay and Aunt Lyn were the ones who encouraged me to study medicine.

JA ***That seems to have influenced your choice of career?***

CM I don't recall it doing so. I liked nothing about that isolation ward. Although it probably made me more empathetic. I was just alone there most of the time. I had an uncle, Jay, and an aunt, Lyn (the one who visited me) —both were physicians. I was in their wedding in 1945 as the ring bearer, and they have this great picture of me in a top hat coming down the aisle. I looked just like my uncle. And the story—probably an urban legend—is that everyone was clucking because I looked so much like I was their kid, and it was time they gave me an honest name. I've been really close to them all of my life. They were the ones who encouraged me to study medicine.

My Aunt Lyn —after being a pediatrician for a while— escaped to psychiatry, where she could better control her hours, and ended up as a faculty member at the University of Illinois Medical School during my years there as a medical student. These are probably not stories to put on the tape, but she actually saved at least two of my classmates from getting kicked out. There was a fairly sick psychiatrist there, who one day was telling everybody, "Just say what you think." And I had a good friend—I won't say his name—who was the most outspoken, boldest-speaking person, who used language that no one used back then except maybe in a locker room. And he was fairly prone to saying whatever hit his mind, with whatever words were most powerful. He could really make a point.

This psychiatrist and his junior medical students—including my friend—were sitting around a table. And the psychiatrist says to everybody, "You say what you're thinking now, exactly what you're thinking." When it came to my friend's turn he said, "No, no, I don't think I should." "No, say what you're thinking." "No, I don't think you'd like it." Under continued demands to say what he was thinking, he finally did. It was something pretty vulgar about the psychiatrist's female assistant. So the psychiatrist went nuts. "That's awful. You don't belong in med school! We're kicking you out! You're sick, you're sick!" [laughter] The psychiatrist wanted my friend thrown out of med school because he had acceded to his request. But my aunt interceded, and my friend survived to become a dermatologist.

JA ***Where I was going with my last question was, I know that you had experience working in a county hospital.***

CM Yes. I spent my med school surgery rotation at Cook County. I had a great resident who went on to become a prominent Chicago chest surgeon. I worked very hard and learned a lot. I have great memories of really tough patients, both in the sense that they had difficult problems and in the street-tough sense, but the toughest ones pitched in, helped the other patients. Back then, county hospitals were the premium places to train. The situation has changed somewhat since then, but certainly in my days growing up, you would hear, "Oh, he trained at County," or "He's seen it all, he can do it, he can take care of anything." So there was actually an aura to County training as I was growing up, although then it was also known as a hospital for the poor and not, necessarily, a good place to be sick.

Back then, county hospitals were the premium places to train.

DS ***Then you trained at Boston City Hospital as well?***

CM Yes.

DS ***Another county hospital and a pretty rough place.***

CM Not so rough, but long hours and intense. But that experience is another story.

JA ***Let's go back to your training. What motivated you to go into medicine? I know you were interested in computers at the same time, so let's take those two together.***

CM Well, I liked science. My younger sister, Peggy, and I took care of injured animals in our bedroom closet, on a couple of occasions. One was a wild rabbit that had a broken leg; it was a very intense experience. It died. But we weren't trained, so what did we know? I also was certainly influenced to consider medicine by my aunt and uncle mentioned earlier: "It is a good field. You should think about medicine."

So that was in grammar school, and maybe I thought that medicine would be a good field then, but I liked all the high sciences—physics, math, chemistry— and liked reading physics and Einstein.

When I started college, I signed up for two majors: pre-med and physics. For two and a half years, I took all of the requirements for both—a lot of courses. I didn't like math in high school, but I fell completely in love with it in college. My freshman calculus teacher was spectacular. He persuaded me to enter the freshman math contest, with theoretic and abstract math questions. I won second place. The prize was a math book.

But as a result of the double major, I was taking tons of course hours, 20 to 21 semester hours, which translated to 30-plus class hours per week because of the many labs. There was nothing else to do at Notre Dame, so I got pretty disciplined in the work of studying. But I concluded after two years that I didn't like physics laboratory at all. That made it relatively easy and helped me choose medicine over physics. I kept taking math courses even after I dropped my physics major. In my sophomore year, I figured I could graduate in the next year if I could just complete eight more credit hours in one summer school, to reach my 132-semester-hour requirement. So, I did. I looked at the liberal arts guys, taking 16 or so hours—playing basketball in the afternoon and cards in the evening—as having a big vacation.

Personal collection of Clement J. McDonald.

Third year at Notre Dame University, Clem in his Lyon's Hall dorm room, circa 1960.

Courtesy Katy McLaughlin.

Clem, as a groom's man, escorts Mary Roach, mother of Bob Roach, the groom (unpictured), down the wedding aisle on November 30, 1964. When Clem and Bob were 3 years old, they played in the alley between their apartment buildings. Clem recalls, "Mary Roach was a loving and tough police officer who was widowed when her children were toddlers."

JA ***How many years did it take you to graduate?***

CM Three years and 132 semester hours.

JA ***You graduated from college in three years. Then you went to medical school directly?***

CM Yes. I told you about the choice of the med school—I didn't worry about choices then. Dr. Scuderi was a successful orthopedist, both of whose daughters I knew and dated—one was a year behind me and the other was a contemporary. I asked his advice: "Where should I go?" He said, "Well, Clem, where you learn to study is not in a classroom but on your butt. It doesn't matter what school you're at, you're going to do the same studying of the same books sitting on your same butt." "Okay." So I went to Illinois. I explained yesterday that most of the senior faculty at the University of Illinois came from the Harvard service at Boston City Hospital. It was these faculty members at the University of Illinois who persuaded me to apply to all the Harvard medicine residencies. And they thought Boston City—also a

He said, "Well, Clem, where you learn to study is not in a classroom but on your butt."

Source: Personal collection of Clement J. McDonald.

Medical interns and colleagues at Boston City Hospital, June 1966. The class included Clem McDonald (4th row, far right), (seated next to Clem, right to left) Norman Jensen, Thomas Bodenheimer, Tom Cesario, and Charlie Langston. Also in the 4th row, from left to right, Bernie Aserkoff (4th row 2nd from left), and Phil Caper (4th row 4th from left). The Chief Resident was Lerry Seidel (2nd row, center). Residents included Robert Knopp (3rd row, 2nd from left), Peter V. Tishler (2nd row, 3rd from left), Steve Schroeder (3rd row, far right, in front of Clem), Wylie C. Hembree (3rd row, 5th from right), and Robert Glickman (3rd row, 3rd from right). Also in the class: Roger Mark (not pictured). In the front row, Charles S. Davidson, MD, Associate Director Harvard II &IV Medicine Services (2nd from left), and Maxwell Finland, MD, Director, Harvard II and IV Medical Services (center).

county hospital — was an especially good place. So I did apply, got in, and it was a great place. `

DS ***What about medical school?***

CM Let's see, I can remember we had a medical school fraternity house, and I had more fun in med school than college because it was like being a monk at Notre Dame. Medical school was hard work, but not as hard as Notre Dame. Chicago winters are fierce. We had to walk back and forth from Ashland Avenue, where we ate lunch in a fraternity house, about three blocks, to where the classes were. The Chicago winter wind would just go through you like flying icicles on that walk. Then you'd walk into the kitchen of the fraternity house, where a gas stove was going full blast for lunch. "Ah, toasty!" It really felt good to get out of the cold. We had a big African American lady who was the cook with a sweet kind of round, southern voice. I would sometimes drive her home after dinner. She lived in the projects but would not let me drive all the way into them. She'd smile and say, "You know you can't do that." And we were all in that kitchen when the radio announcement came about Kennedy's assassination, and everybody stopped talking, and people started sobbing.

We were all in that kitchen when the radio announcement came about Kennedy's assassination, and everybody stopped talking, and people started sobbing.

JA ***When did you get interested in computers?***

CM Computers. Senior year in medical school was my first real project. But, I guess I was always interested in how computers really do this "thinking" thing. What were they really doing when they "thought?" That philosophic question kept my interest in computers percolating. We didn't have a computer center at Notre Dame until the year after I left. So there weren't any good opportunities in my early years. I learned that computers don't do anything as profound as I thought when I finally dug in and figured them out.

In med school, I read Homer Warner's[24] 1961 *JAMA*[25] and 1964 Annals of the New York Academy of Science[26] articles on computer diagnosis, and they stimulated me. There's a guy named William Best, who until recently was a leader in informatics in the VA [Veterans Administration, now U.S. Department of Veterans Affairs]. In the '60s, he was at the VA computing center in Chicago, part of the medical center where the medical school stood. I was directed to him as the guy that was doing mathematical computer things, and I asked him if we could duplicate Homer's computer diagnosis work, and he said, "Well, that's an interesting problem."

The Bayes equation was easy enough to program, so we decided to apply the Bayes approach that Homer Warner used but applied it to the diagnosis of the acute abdomen. There's a little book by Cope, which I think is still published, that describes the 50 things that cause acute abdomen and how you discriminate among them. However, the differences were all described in narrative. We had to convert that descriptive text into statistical rows and columns, with a lot of guesses, then we collected some surgical cases to test our system. I think I only abstracted a total of five test cases, from

Source: Personal collection of Clement J. McDonald.

Clem, circa 1965.

their medical charts. By then, school was over, and we hadn't achieved much.

After my internship, I went to Northwestern University [in Chicago] to obtain a master's degree in biomedical engineering. While there, I ended up restarting the computer diagnosis project I started in medical school. We tried a number of mathematical methods, including Bayesian, k-nearest neighbor rule, and discriminate functions, and maybe a fourth one. For that effort, I abstracted 73 charts of patients with the acute abdomens (appendicitis, acute cholecystitis, etc.) to test the success of these methods. That was not many cases, but it took weeks to abstract them. The best that any of the methods could do was about 63 percent correct.

I guess I was always interested in how computers really do this "thinking" thing.

DS ***How did you get to the NIH?***

CM In my senior year of medical school, the same guys from Boston City said, "You should apply to NIH. You have to apply now for the future." So I applied to the Public Health Service CORD [Commissioned Officer Residency Deferment] program at NIH. What I applied for was a fancy mathematical modeling position. I believed that math could do anything. I mean, you could just figure it out with math. In the extreme, you could take Schrödinger's quantum mechanics equation, start with small molecules, add them together to make a cell, and finally, you could figure out a dog. You know, just compute a dog. I was really naïve, very naïve. Today, giant computers cannot yet model more than a few dozen amino acids.

But I did stay with one noncredit course—in jujitsu.

Source: Personal collection of Clement J. McDonald.

The Akiyama family -- (left to right) Tomo, Yoko, Tet, and Noriko Akiyama -- visited Indianapolis from Hamamatsu, Japan, in October 1981. Clem recalls, "Tet was my jujitsu instructor at Northwestern in 1966. We have remained friends ever since and have had visits on both sides of the Pacific."

The program I applied to was not quite as exotic as my imagination. This'll be the beginning of '65 or the end of '64, I don't remember exactly. I went and interviewed, and I didn't get that job, but NIH sent my resume to other parts of NIH. Then, during my internship, I got an offer from NIH to do a different job. It was in the Pathology Department of NIH's hospital [the Clinical Center]. They were working on a computerized laboratory system and wanted somebody to come and help them. That seemed okay, but it did not involve any exotic, deep math, just data processing, which I initially looked at with some disdain.[27]

DS ***Even then you looked at it with disdain?***

CM No, not after I started.

And then as an intern, I became aware—I don't know really how—of a master's program at Northwestern in Chicago. Maybe the NIH guys told me about it. I could take that and defer my arrival at NIH. I loved Boston City Hospital, but I didn't like Boston; I wanted to go home, and Northwestern was in Chicago—home.

DS ***When you say "defer," from what?***

CM The NIH program was the Public Health Service's CORD program. Members of the CORD program would be officers in the Public Health Service—one of the uniformed services—so the CORD program satisfied military service obligation, if you were accepted. I wasn't trying to get out of the military, but everyone told me, "You need to go to NIH." So I ended up being the

third MD in this Northwestern bioengineering program and the first MD to graduate, because the first few MDs couldn't do the math.

I loved the program. I could just go and take any course. It was like heaven. I signed up for a lot of noncredit stuff, like a Shakespeare course, but I didn't get to most of those classes.

But I did stay with one noncredit course—in jujitsu. The teacher was a PhD student from Japan. His name was Tet Akiyama, and I remember that first day. It was a freshman physical education class. I was fit. I was running and lifting weights. This guy was about 155 pounds and almost six feet—pretty skinny, I thought. So he's throwing some little kids, who were smaller than me, and I'm thinking, he's not going to throw me. And then he gets to one of the 220-pound football players. The football guy didn't go quite as high in the air, but he went down just as quickly as the other kids in the class. Okay, he's going to throw me. Tet and I ended up becoming good friends. His family visited us a few times in Indiana, and we visited him once in Hamamatsu. That was the gravy to the experience.

It was the era of punch-card computer programming. If you get one tiny little error, it's another two-hour cycle before you get back a printout, to tell you that you typed something wrong.

At Northwestern University, I started with two projects. The first was suggested by this German postdoc in molecular biology. He said, "What you should do is isolate messenger RNA for hemoglobin. It's not been done yet." Recall that I am a master's degree student, and I'm not a biologist. So I killed maybe a hundred rabbits during that time. The task required maybe 80 or a hundred sequential steps, and if one step failed, everything failed. One step always failed. So I never isolated what we could really, for sure, say was messenger RNA for hemoglobin.

Then I tried another project where I was trying to compute out the separate peaks that add together to form the blended humps in results of an ultra-centrifuge run. You could, in theory, actually quantify from prediction algorithms the exact amount of each of those molecules from the blended curves. I think it has been done since. So I worked with that for a while, on a basis of pure math. That one didn't work out, either. You've got to realize, it was the era of punch-card computer programming. If you get one tiny little error, it's another two-hour cycle before you get back a printout, to tell you that you typed something wrong. Then you fix the program by changing instructions on the punch card and wait another two hours, and the cycle repeats over and over again. It took days to get a program that would run but still not work. Then you had to find problems with the logic. It was amazingly impossible. I don't know how anyone accomplished any programming tasks back then.

By this time, I'd accumulated, like, 50 percent more credits than I needed for a master's degree, and I went to the guy who ran the program, Dr. John Jacobs,[28] and said, "You know, my projects didn't work out, so can I just get a non-thesis master's?" He said, "No." I was the first MD in his program who hadn't washed out the engineering course work. He was determined not to lose another. I told him, "I don't really need another degree." "Yes, you do," he said. He had worked out a deal with my boss-to-be at NIH [Dr. George Z. Williams] that required I complete the degree. So, I went back to that Bayesian diagnosis problem mentioned earlier, tested three different diagnostic algorithms on about 180 patients, and wrote an 80-page thesis.

At NIH, we built what was, I think, the first computerized laboratory system. I was only supposed to help manage the development, but I could program, so I got in and did stuff. I was also working on programs for the hospital wards. The Pathology Department asked me to stay and offered me a pathology residency with a staff salary, a very good deal, but I wanted to go back to Chicago. My dad always wanted me geographically closer, so he was glad that I came back.

DS ***So you were a pathologist?***

CM No. I had a one year straight medical internship at that time. I also had a lot of ER [emergency

room] experience. During the two years obtaining my master's degree, I worked ERs twice a week or something like that.

JA ***At what point did you become interested in developing clinical information systems, in particular?***

CM Well, I sure thought about it as an intern in '65. Interns were mostly data dredgers, and even then, computers were replacing data-gathering work at banks. We spent way more time gathering data than caring for patients, and it just seemed like such a bad waste of time. I also had to invest oodles of time chasing after those lab results at Boston City and later at Cook County. But for sure, after work at NIH, it was clear that this data-processing stuff was neat and could solve a lot of problems.

We spent way more time gathering data than caring for patients, and it just seemed like such a bad waste of time.

There were many elegant approaches to efficient disc-storage access and search algorithms. There was actually a lot of deeper stuff. I mean, it wasn't just, try something and see if it works. There was a theory to it, and so I was strongly influenced by that lab system development experience. If you can do the lab, you can figure out how to do the rest of a medical record system because the core of the medical record is a stack of clinical variables that look a lot like lab results. And, of course, the medical record system also includes laboratory results.

The core of the medical record is a stack of clinical variables that look a lot like lab results.

At the end of my time at NIH, I wrote a letter to the Chief of Medicine at the University of Illinois medical school. I was looking for a place to finish my medicine residency and asked him about the possibility of a faculty position after my residency.

I wrote a long, detailed, three-page, single-spaced letter to him, describing exactly what I wanted to do. I wanted to build a medical record. I wanted to work with the medical staff to get it working, and I wanted to stay in academics. I wanted to know if there would be any possibility of funding, or if there'd be interest in such an arrangement. I had a pretty good CV, so I thought at least I'd get some discussion. He sent back a one-line note saying, "You come and be a resident, and when you finish, we'll talk." I considered that a non-response. I went back to Chicago without a job and started to work ERs and goofed off for a couple of months. I was going to write the great American novel, but it was too hot. [laughter]

DS ***You mean the novel was too hot?***

CM My apartment was too hot.

JA ***He had his little loft apartment—.***

CM Well, actually, I was on the ground floor—.

DS ***I thought maybe the novel was too hot. [laughter]***

CM No, no, no, it was Chicago in the summer. This apartment was an add-on to a large house on the near north side of Chicago, where five of my old buddies lived. I sublet it for the summer. The woman who had the lease had gone to Alaska. The table on which I tried to write was above a basement. In the basement below was a large hot-water boiler shaped like a huge bologna and lying horizontally in a cradle. It had no insulation. The apartment had no air conditioning, and the neighborhood was not congenial to open windows. Chicago gets warm and humid in the summer, so it would get really hot in that place. I would start to write on this big wooden table in the middle of the room—right above the boiler—and I would fall asleep. So, no great American novel. Nothing at all.

DS ***So you have no job—.***

CM I had no full time job, but I was earning enough money as an ER doc. I had a decent reputation. People found out about me, and I got a couple offers. One guy asked me to come and be the Director of a very large clinic in a poor, really tough neighborhood, at a fairly large hospital that was going broke. The guy

took me out, and we talked. He was very idealistic, very committed, and a good guy. I had no experience running anything, let alone a large clinic. He told me there was no money. I was flattered, but I thought (almost out loud), "I don't know how to do this!" So I didn't.

Rolf Gunnar, who became the Chairman of Medicine at Cook County a few years earlier, had been building up the Department—improving service, adding medical and nursing staff, improving the quality, and creating a real research program. He consulted on a surgery patient while I was a surgery medical student at Cook County. I suggested that the patient might have an amoebic liver abscess, and I was right—so he remembered me. When he heard I was "loose" in the city, he asked me to meet him in his office at Cook County. He said, "C'mon Clem, you can help us." He had this distinct kind of interesting tone to his voice. Sort of an accent, but he grew up in Chicago. "You can help us here."

I would start to write on this big wooden table in the middle of the room—right above the boiler—and I would fall asleep. So, no great American novel.

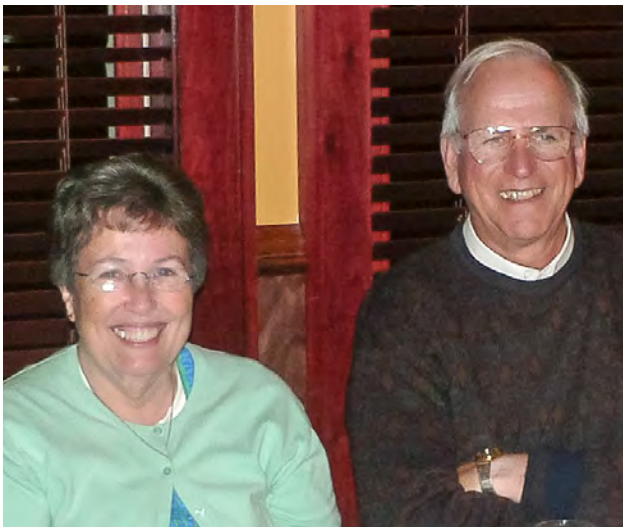
I asked him all the same questions I asked in my letter to the chairman of University of Illinois College of Medicine. "Sure, we'll guarantee that. You can do all that." He was a good man, and he loved Cook County Hospital. But then, at the end of my first year of residency— a great year—politicians forced him to resign because he was making the place too good—my interpretation. His dismissal was very ugly and completely unjustified.[29] He urged me to stay, being loyal to Cook County Hospital even in the face of its disloyalty to him. No way, I thought. Rolf went on to become a very successful Chair of Medicine at Loyola Medical School in Chicago.

At about this time, Warner Slack,[30,31] a famous medical computer guy at U. of Wisconsin, had taken a position at Harvard,* so his boss, Robert Schilling—of Schilling's test fame [the test for pernicious anemia]—was looking for a replacement. My computer mentor in medical school, William Best, was also a hematologist and a friend

* An oral history interview has also been conducted with Warner Slack as part of the NLM Medical Informatics Pioneers oral history collection (https://lhncbc.nlm.nih.gov/project/medical-informatics-pioneers), which also carries fascinating histories from other medical informatics luminaries.

Source: Personal collection of Clement J. McDonald.

Joe Mamlin is a committed fisherman, and patiently taught my sons, Christopher (pictured) and Clem III (out of view), how to fish with a casting rod, circa 1984.



Source: Personal collection of Clement J. McDonald.

Sarah Ellen and Joe Mamlin, circa 1995. Clem recalls, "Joe Mamlin was my boss for 25 years and supported all of my informatics efforts mightily."

of Schilling's. Given the turmoil at Cook County, Dr. Best conveyed to Dr. Schilling his belief that I might be interested in a different position.

Dr. Schilling came down from Madison, met me for breakfast at Greeks, a bar across the street from Cook County, and he said, "Why don't you come up and be a medicine faculty member? Take Slack's position. I know you want to do computer things." I was tickled by his interest. But, I reminded him he was offering a faculty position, and I hadn't finished my medicine residency yet. So he offered to let me finish my residency in Madison, and I accepted. At Wisconsin, I met a guy [John H. Grist]—a psychiatrist and computer guy—who had worked with Warner Slack. He grew up in Indianapolis and knew about Wishard Hospital and the Regenstrief Institute in Indianapolis. He knew Regenstrief had an interest in medical computing and Wishard was a county hospital, which he thought I would like. So he suggested I interview there, and I did.

> I wanted to computerize medical records, and the Regenstrief Institute liked that idea, though they probably didn't know what it meant or how big of a challenge it would be.

DS ***What year was that?***

CM Dr. Schilling interviewed me in late May of 1971, and Joe Mamlin, the Chief of Medicine at Marion County General Hospital (later renamed Wishard Memorial Hospital) interviewed me later that year. I came to Regenstrief in February of 1972.

JA ***What was Regenstrief Institute like when you arrived here?***

CM Well, if you want stories—. It was February of '72, and on day one, I was assigned to staff residents on the hospital ward. I had apprehensions about being staff at a university-affiliated hospital. I wasn't a subspecialist. I did not have tons of clinical experience, and it was definitely a take-care-of-people hospital with very sick patients. Though I didn't know everything about any one thing, I could decide what to do next. The residents would say, "What should I do?" I would tell them, "Do this." I'd make a decision, whereas many of the specialty consultants would waffle: "Well, we need to think about this, and think about that," without making a decision. So I was successful.

My first day of rounds followed immediately after a trip to Peru to be the best man in my good friend Jim Kearney's wedding. On the way to the wedding, I stopped in Cuzco, which is 10,000 feet above sea level. I knew about altitude sickness, so I brought along a diuretic (Lasix), and, of course it's also a place where tourists get "Tourista" [Travelers' diarrhea], so I brought along some Lomotil for that—both little white pills. I didn't need either on my trip, but on the morning of my first ward rounds, I perceived a bit of gurgling. So I thought, "Gee, if this gets bad, I should bring along a little Lomotil," and I put one in my shirt pocket.

The gurgling persisted as the residents presented their first patient. So I popped the white pill into my mouth and swallowed it without water. Then, all of a sudden, I felt something strange growing rapidly in my abdomen, like a fetus planted by an alien. What I'd actually put in my pocket was the Lasix, the diuretic. And in a healthy young person with good kidneys, Lasix opens the sluice gates. So what I was feeling was my bladder growing like a balloon on a

Source: Personal collection of Clement J. McDonald.

Clem and Barbara McDonald, just married in El Paso, Texas, June 30, 1973.

Source: Personal collection of Clement J. McDonald.

Pilatus porter PC-6, taking off on short dirt runway at Syangboche airport (elevation 12,402 feet, the 4th highest in the world), circa September 1973. The PC-6 could take off with 600 feet and land with only 400 feet of runway. This airport was built for a brand new hotel called Everest View Hotel, but after many deaths due to high altitude sickness the hotel and airport were closed. The hotel later re-opened. The airport was re-opened only for supply and emergency evacuation flights until recently, when charter flights were allowed. Video available at: https://www.youtube.com/watch?v=DqgZvb37NX0

water spigot. I spent most of my first rounds running back and forth to deal with the flow. Not an auspicious beginning.

JA ***So how did you first come to Regenstrief?***

CM Joe Mamlin was the key. In the late 60's, he served in the Peace Corps, in Afghanistan. He wrote the first Afghan textbook of medicine—written in Pashto (the national language of Afghanistan)—for the medical school up in Jalalabad.[32] He is a powerful personality, very effective, and a deeply good human being. He was Chief of Medicine at Wishard Hospital. I can remember what he said when he dropped me off at the airport for my return flight to Madison: "Clem, I want you to do what's best for Clem. Whatever is best for Clem is what I want," and he meant it.

And I was maybe his fourth hire, or fifth hire.

JA ***Ever?***

Source: Personal collection of Clement J. McDonald.

During their honeymoon, Clem and Barbara trekked from Thengboche to DingBoche, villages on the way to Everest. At altitude, the sky is cobalt blue and gorgeous, but the clouds rise up in the afternoon and obscure the view.

Source: Personal collection of Clement J. McDonald.

Barbara in Kathmandu, Nepal, 1973, waiting for the rains to stop so the airplane to Everest could take off. Flight was delayed for three days. Clem in front of Sherpa Hotel Pheriche at 14,300 feet, Mount Everest area, Nepal, circa September 1973. The beds were wood benches, but fatigue trumped discomfort, and sleep was immediate. A high-altitude research clinic was founded nearby, at about the same time Clem arrived (http://www.himalayanrescue.org/hra-pheriche-aid-post.html). Today, Pheriche has many modern hotels.

CM Yeah. I mean, he didn't have much staff.

DS ***Is this the Department of Medicine?***

CM It's the general medicine section of the Department of Medicine. The IU School of Medicine had three hospitals—Wishard, IU Hospital and the VA. The sections at each hospital were fairly independent from each other back then. Wishard (my hospital) was the favorite teaching hospital, because the university hospitals are always referral hospitals—they have mostly diagnosed cases sent in for specific treatment.

Source: Personal collection of Clement J. McDonald.

Barbara and Clem, first Christmas together in Indianapolis on Landsdowne, 1973.

JA ***But he had also selected you because of your informatics?***

CM I think so. Maybe he would have taken any warm body, but he was never scheming. I'll have to ask him someday. Regenstrief was linked to Wishard and IU. Wishard was a separate organization controlled by the County. The Regenstrief Institute was created in '69. Its goal was to do systems studies and use technology to improve healthcare—not biology research. I wanted to computerize medical records, and the Regenstrief Institute liked that idea, though they probably didn't know what it meant or how big of a challenge it would be. I told them what I wanted to do, and the Institute, headed by Ray Murray, thought that it certainly fit within their scope. There was a PhD engineer from Purdue who was being put through medical school by the Institute, to become a future asset for medical computing. Regenstrief bought him a minicomputer—I think it was a Digital Equipment PDP 11-44. They located it at Purdue, 60 miles away, and we were connected to it by telephone wires and slow modems.

JA ***So you had that person as a colleague, too?***

CM The idea of a sophisticated decision theory guy being around was one more incentive for me to come to Indiana. But he was almost never around; he had only recently finished his PhD (or his postdoc) and inherited a huge grant from his boss, who was promoted to be the Dean of Electrical Engineering. Everyone characterized him as a wunderkind. He was an interesting character—he wore a gold lamé suit to one of our Regenstrief parties.

At that time, Eugene Stead was the Foundation Director of the Regenstrief Institute.

DS ***Oh! Was he living here?***

CM No, he'd come once a month from Duke and spend three days or something like that. John Hickham had been the Chairman of Medicine at IU and orchestrated the idea of the Regenstrief Institute, both to get the University better connected to Wishard Hospital and help build up the Department, and to study the operation of a care institution and improve it. Hickham, who was loved and revered at IU, died at age 50 from a brain aneurysm before I arrived. That's why Eugene Stead came to help out, because Hickham was one of Stead's protégés, and one of his favorites. Eugene and I had some fights because I didn't know enough—I was just a Midwest kid.

> Well, it's hard to switch from what you start with.

DS ***Didn't know enough to respect him?***

CM I didn't know anything about Duke. I'd never heard of him. I didn't know at that time 50 percent of departments of medicine in the U.S. were run by his trainees. He was just this guy that came now and then. And he called me in to tell me, "Clem, here is what you're gonna do"—I could, at one time, imitate his drawl—"you're gonna go around the state and set up care sites around the state. We're gonna take on the whole state and make a real care system out of it." I said, "I'm not doing that." "No, you don't understand," he said. I said, "Yes, I do, but I am not doing that. I came here to work at Wishard, not to drive all over the state!"

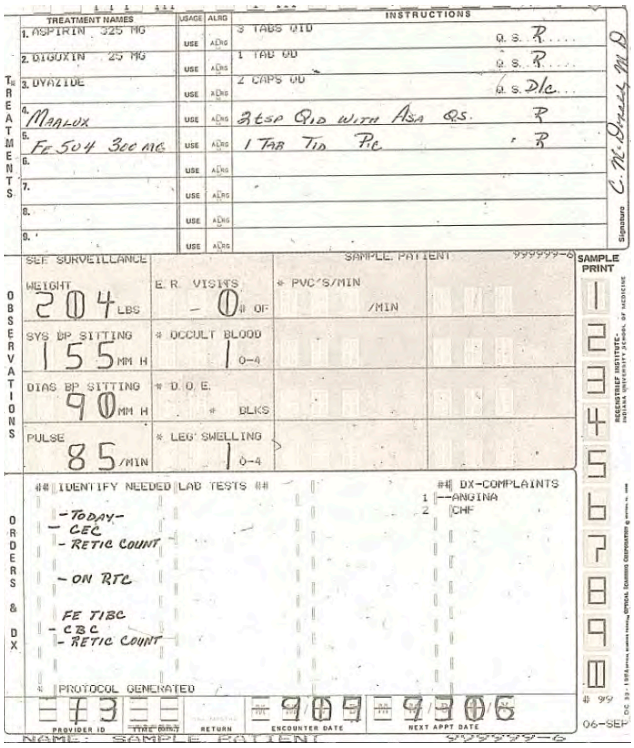
DS *He did have a vision, didn't he?*

CM He got mad. He said, "You'll be a nothin'! You'll be a nobody!" But we came to be friends. He invited me down to his home at Duke University. And that's where I met Bill Stead when he was a junior in medical school. And later, Eugene actually tried to hire me for Duke. Looking through stuff recently, I just came across a 1980s letter from Eugene that was very nice.

Around this time, I married Barbara, a longtime friend. She worked for Pan American Airways, which offered employees a 90 percent discount on any flight. So for our honeymoon, we looked for the most distant place with something interesting.

We ended up flying into Delhi, then Kathmandu, and finally the Mount Everest area. For that last hop, we landed at Syangboche airport with a teeny dirt strip at 12,400-feet elevation [see picture on page 14]. It had only recently opened, then closed two years later, so Lukla—a larger airport at a safer lower, altitude—was able to win title of the world's most dangerous airport during its 40-plus years tenure. We had no idea. Syangboche airport[33] was built for the Everest View Hotel[34] (elevation 13,000 feet), where we had reservations.

The schedule for the hotel's initial opening slipped a month; so they had to put us up in tents. Altitude sickness touched us both, but the mountains and sky were gorgeous, and we came back with lots of stories.



Source: Personal collection of Clement J. McDonald.

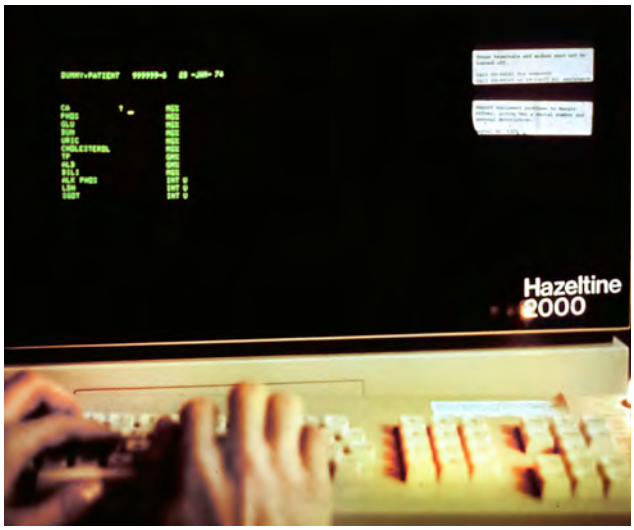
Regenstrief's first EMR, starting in 1972, was based on paper turn-around documents. The encounter form was produced the night before the visit and tailored to the patient. Some of the data were entered via optical character reader (OCR) and some by clerks.

JA *And at that point, what were you doing, as far as systems go?*

CM Well, let's see. That could have been a year into our project, or early 1973, when our electronic

Source: Courtesy of Regenstrief Institute.

Printer, circa 1973, Regenstrief Institute. Used to print encounter forms, flowsheets summaries of patient EMR data, and reminder reports, the night before the patient's visit. The printouts were placed on the front of the patient's chart the day of their visit.



Source: Courtesy of Regenstrief Institute.

Hazeltine 2000 monochrome video terminal, used to enter patient data for Regenstrief medical record system. We used another Hazeltine terminal for programming. The 1974 H2000 specifications are described at http://www.columbia.edu/cu/computinghistory/h2000.html

medical record (EMR) was operational in the diabetes clinic, where we were doing our first randomized trial of reminders. In June of ’73, it carried 480 patient.[11] was actively used in the clinic. The system was all based on paper documents specialized to the patient, an encounter form, a patient data summary, and a reminder report. It had to be paper. We only had four ports to which we connected two terminals and two printers.

JA ***Was that one of the first opportunities you had to share among true colleagues?***

DS ***Informatics colleagues.***

CM Yeah. It was. And I met Bill [Stead[35]] and Ed [Hammond[36,37]], and they were building neat stuff right at that time, just then and there. Bill, Ed, and I had all the same ideas and concerns. I think we were actually ahead of the places on the coasts regarding operating medical records, though we were relatively unknowns.*

DS ***Is that right? I think Bill had long hair at the time.***

CM Yeah. You look at the published papers. You can’t really get people nailed down, about when a project was a thought and when it was actually running.

DS ***That’s still the case in our field.***

CM Yeah.

JA ***Were you able to talk to the people in Boston, though, and share ideas?***

CM Visits to Boston didn’t happen until after my ’76 paper in the New England Journal of Medicine.[4] In fact, for those early years (till ’76), I hardly travelled. I think I went to three meetings in my first four years, and I just mostly worked to build this medical record. I was working alone for about a year or so, and then I got one programmer.

DS ***So were you writing this in MUMPS [Massachusetts General Hospital Utility Multi-Programming System is a general-purpose computer programming language] or assembly language?***

> The person who answered would say, “I’m one of the programmers. What do you want to know?” And we would get our problem solved.

* Oral history interviews have also been conducted with Bill Stead and Edward Hammond as part of the Medical Informatics Pioneers oral history collection (https://lhncbc.nlm.nih.gov/project/medical-informatics-pioneers), which also carries fascinating histories from other medical informatics luminaries

Source: Personal collection of Clement J. McDonald.

The Regenstrief computer room, circa 1975. Their DEC PDP-11/45 computer was a 16-bit minicomputer sold by Digital Equipment Corporation (DEC), part of the Programmed Data Processor (PDP) series.

Source: Courtesy of Regenstrief Institute

Clem (standing, left), Margi Guiou (seated) and Jim McKee (standing right), in the Regenstrief computer terminal room, circa 1974.

CM No, in Digital Equipment Corporations (DEC) BASIC [Beginner's All-purpose Symbolic Instruction Code] a high-level interactive programming language.

DS ***You've been a BASIC man all your life.***

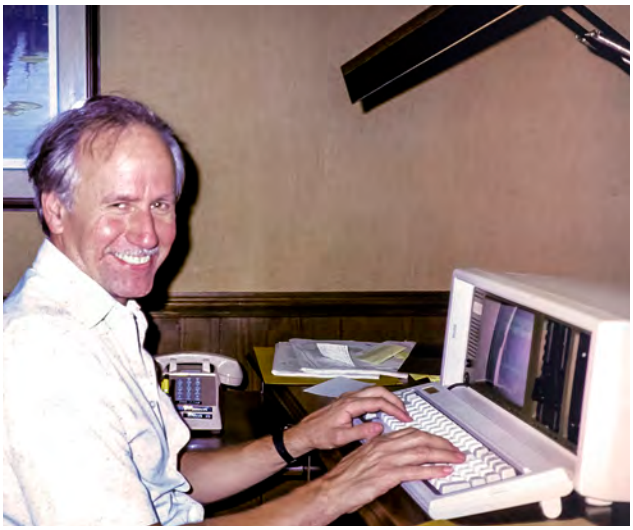
CM Well, it's hard to switch from what you start with. So we never did MUMPS, but I respect MUMPS, because starting in 1983, I programmed the first version of the Gopher physician work station in Revelation on a portable Compaq PC (with Burke Mamlin's help), and Revelation had many analogies to MUMPS. It had a built-in database that used hashing to access the data instead of the better B-tree index approach that MUMPS used. Revelation had big variables and subroutines (both 64k bytes), larger than what MUMPS allowed. Revelation was a PC implementation of the Pick operating system.[38] [The Pick operating system consists of a database, dictionary, query language, procedural language (PROC), peripheral management, multi-user management and a compiled BASIC Programming language.] It was used to develop all kinds of niche systems, a sort of blue collar developers' system. I don't mean that derogatorily, but to describe its use by more industrial, brawny kinds of companies, such as body shop repair systems. We picked Revelation in which to develop our physicians' work stations because we couldn't find any other software company with humans who would answer a phone. We looked at Digital Research. Their PL-1 language was tempting. And we looked at Microsoft. However, when you tried to reach them, they both seemed to be illusion. No matter how hard you tried, you couldn't reach any humans. They had phone numbers, but no one answered.

Source: Personal collection of Clement J. McDonald.

Clem at the Indy500 practice, circa 1975.

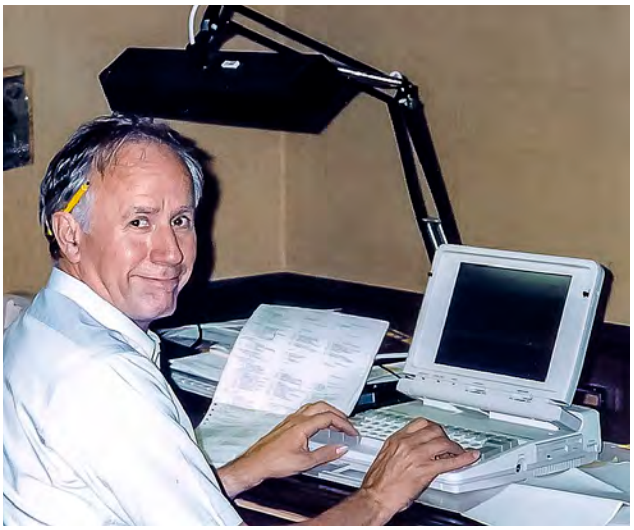
JA ***Some things never change.***

DS ***I was going to say, it's amazing how little things change in 20 years.***



Source: Personal collection of Clement J. McDonald.

Clem's office at home, circa 1983, with his Compaq portable (luggable 30-pound) computer on which he developed the initial Gopher Physician's workstation. It had no battery, so always had to be plugged into AC power.



Source: Personal collection of Clement J. McDonald.

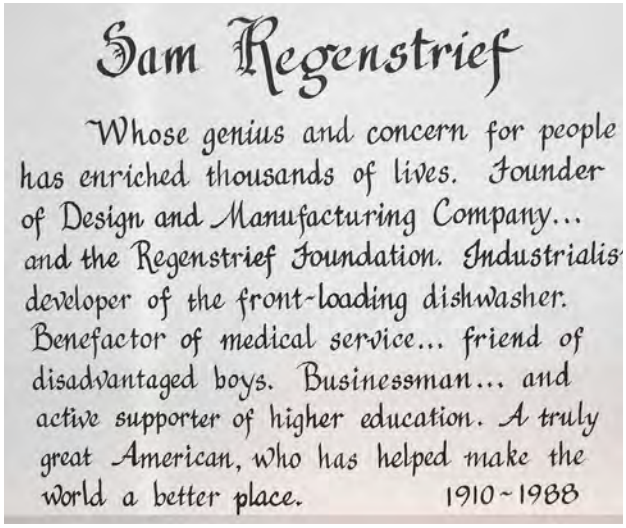
Clem, summer 1988, at home with new "lightweight" 14.5-pound Zenith SuperSport 286-40 computer. This Zenith had 40 megabytes of hard disc space and a list price of $5,900. It also had a battery, so Clem was not tethered to AC power as he was with the heavier Compaq. Clem moved the development system for the Gopher physicians' work station to this system. Four years later, he got a 7-pound Zenith MiniSport and recalls, "That was heaven."

CM I would call Revelation and say, "I want to talk to a programmer." The person who answered would say, "I'm one of the programmers. What do you want to know?" And we would get our problem solved. Furthermore, Microsoft BASIC was horrible in 1984. The weaknesses were especially obvious because we'd been working with Digital's VAX BASIC,[39] a sophisticated, rapidly compiled BASIC with all of the then modern structured language statements. The supposed advantage of an interpretive language is that you should be able to stop it, change the code, and keep on going. With compiled language, you have to recompile it, and then you've got to do all the start-up stuff. Well, Microsoft flushed everything as soon as it got an error. So, you had to start all over again anyway, even though it was an interpreted language. And, it gave no warnings about illegal programming statements as you wrote them, as VAX BASIC and Revelation BASIC did.

DS ***They haven't changed much, either. [laughter] It's amazing.***

CM I do have to say Visual BASIC from Microsoft was a new and better world, and their latest development system is a dream. However, Digital's [Digital Equipment Corporation (DEC)] VAX BASIC -- the language in which we developed the Regenstrief Medical Records System -- was really nice. It caught illegal statements as you typed them, compiled in seconds, and let you stop, look at content, and continue to run. And it was the same with Revelation—it'd tell you, "That's illegal, this isn't right, it won't compile." So that's how we ended up on Revelation.

So bring me back.



Source: Personal collection of Clement J. McDonald.

Dedication plaque in recognition of Sam N. Regenstrief. In 1967, when he created the Regenstrief Foundation and Institute, Sam complained that "healthcare was way too expensive" and provided the original funding for the Regenstrief Medical Record System.

Source: Personal collection of Clement J. McDonald.

An award presented to Sam N. Regenstrief listing all of the dishwasher brands he manufactured.

JA ***We're back at—let's see: What was it like in the beginning, when you first started? Were you on this floor?***

CM Oh, no, no, no. From '72 to early '75, we were in the 3rd floor of the yellow brick building along Tenth Street. It's historic, built in the late 1890s or early 1900s [see picture on page 21]. Pigeons would congregate in the windowsill and coo all day. Wishard had a couple of famous people back then when it started. The Hospital's namesake, William Wishard, invented the field of urology.

JA ***What was it like?***

CM It was clinically busy, so I was rounding on the inpatient side three months a year, and two or more half days in

the clinic every week. The clinic had 12 or 13 residents, and the clinical side was a ball. At the County hospital, you get a lot of people who are disadvantaged, who have diseases that are advanced, but which you can often fix. Maybe you have to work hard to fix them, but you can help. The university hospitals more often have people who have already been well cared for by their local doctor, or have an intransigent problem, and there is less to improve on. A physician could make more of a difference at Wishard.

Source: Courtesy of Susan Luse, Richard M. Fairbanks Foundation, Inc.

Len Betley (left), President of the Regenstrief Foundation for some decades, and Steve Sample, a Foundation board member, circa July 1996. Sample was the President of University of Southern California from 1991 to 2010.

There was a lot of struggle. Joe ended up taking over the Hospital from an organization of private physicians who were politically connected. He got control of the budget. The building we are now in was completed in '75 with $2 million of Sam Regenstrief's money. I think it took $8 million to build the building. The other $6 million came from a bond issue. The sixth floor was intended for the private practice group who controlled the public hospital. The top floor has these little indents covered with black stone. Those indents were originally planned to be windows. None of the five lower floors were planned with windows. And all the rooms on the sixth floor had bathrooms. That all changed to save money on heat and air conditioning when Joe took control; no windows and few bathrooms.

At the outset, one-half of the fifth floor was Regenstrief Institute space, and we had our own computer and many more ports by that time. The rest of the full floor's worth of space, paid for by Regenstrief, was distributed through the building. The goal was to have space in the place where the clinical work was going on, and where you could implant researchers, who could be part of the process. That was really Eugene Stead's idea. Over time, Regenstrief Institute has mostly re-aggregated that space as researchers' offices on half of the sixth floor.

Sam Regenstrief was the dishwasher king in the '50s and early '60s [see picture of dedication plaque at Regenstrief Institute on page 20].[40,41] He built 40 percent or more of the world's dishwashers for 15-plus brands in a small town at the eastern edge of Indiana. On one of the Institute's walls is a plaque that lists all of the brands of dishwashers he built. He could make something out of nothing. He would buy an old factory, and rebuild it. He never spent any money on himself, had no kids, and he thought healthcare was way too expensive in 1969! So he wanted to have the Regenstrief Institute re-engineer the healthcare system. He thought computers would be important to that process. Sam Regenstrief described himself as an industrial engineer. He certainly could build efficient factories, but as I understood it, he never went to college.

Source: Courtesy IUPUI University Library Special Collections and Archives

The Regenstrief Health Center, where Regenstrief Institute moved into part of the 5th and 6th floors from the 3rd floor of Wishard's 10th Street outpatient building in late 1975. Medical record system development continued there through Clem's tenure.

He, his wife, and his extended family were completely generous and supported the work of the Institute from the beginning. One of the family members was Dr. Harvey Feigenbaum, who provided scientific guidance to Sam and the Institute board. The medical world knows Harvey as the pioneer and major force behind the

cardiac echo and the author of the primary textbook on the subject.

A most important individual in the Regenstrief Institute success was Len Betly, who was Sam's lawyer and created the legal structure for the Institute, which for a time had the same legal structure as the Howard Hughes Medical Institute Foundation [see picture on page 21]. He was dedicated to Sam's goals and kept the Institute on a steady course when Sam died, and thereafter. He was a longtime believer in medical informatics and facilitated the expansion of the Regenstrief Medical Record System from behind the scenes at many crucial points in its evolution.

Sam encouraged the recruitment of a PhD systems engineer, Steve Roberts, from Purdue shortly after I arrived. That's why we ended up office landscaping, a new thing at that time that turned out to be a really good idea. You have a lot more connection, you see people. You know what your people are doing, because you walk by, they're there, or not there, they're twiddling their thumbs, or watching TV.

JA ***There's a lot of popping in and out of cubicles, too.***

CM Yeah. So I think it's actually good. I was worried about it at first, because of noise interrupting and interfering with concentration and all. That is still an issue. But the soundproofing is very good. However, it took about five years to get people trained to talk quietly.

Now and then, you'd get somebody new in. We actually have an employee down here, when she gets excited, she just roars up by 20 decibels, just piercing. Bill was loud in his early days.

DS ***Bill Tierney?***

Wonderful connections occur and reoccur.

CM Yeah. Oh! He'd get excited about something, and you could hear him across the whole place.

JA ***When did you move into here, then?***

CM Around November of '75. Regenstrief Institute is building a new building now, in a real pretty place.

JA ***Yeah. I was going to ask you about that later, but I may as well ask you now. How did that come about?***

CM The new building that is not yet built?

JA ***Uh-huh.***

CM For at least 10 years, the Regenstrief Foundation promised us new space. Our plan was to remodel the whole sixth floor and put all of the Regenstrief Institute on that one floor, so we would all be together. The Regenstrief Foundation set aside some money for it, but it did not happen. Then, Wishard considered building a new hospital, which stopped everything. But later, Wishard decided not to build a new hospital. It seemed like something always came up that would stall the decision. Len Betly had been saying for years, "Shouldn't the university build some bigger space and better space for the Institute?" and trying to get them to do it.

Source: Personal collection of Clement J. McDonald.

Carolyn and Clem III, exploring Yellowstone with Dad, circa July 1977.

Source: Personal collection of Clement J. McDonald.

Barbara with Clem III and Carolyn, circa June 1977, Grand Tetons.

I threw out an idea. There's the Canal that's really kind of neat—the Indianapolis Canal. It's not San Antonio's level yet but it has pretty bridges, paddle boats, and even gondolas. People are running alongside it. It's very attractive. So I asked Len Betly, "Is there any way we could build on the Canal? It would be spectacular on the head of the Canal." I don't know whether it had anything to do with my inquiry, but that's where the new building is going to be, right at the head of the Canal.

DS ***Wow.***

JA ***Where the old horse barn was?***

CM Yeah. It'll be a very nice space. The disadvantage is it will be further away from the hospital. But there's a train—you see that monorail? It will stop there, and that will mitigate the distance.

JA ***Then my last question, before I turn this over to Dean to talk about publications, is, what do you consider your greatest accomplishment to date?***

CM I want to come back to the Harvard question just for a minute, because of important connections with people there. Howard Bleich[30,31] [an MD informatics pioneer from Harvard's Beth Israel Hospital] has had a very important influence on my career—a small amount of time, but a large effect.* I ran two randomized clinical trials (RCTs) very early in my career. The first study was in the Diabetes Clinic, and we published it in the *Annals of Internal Medicine* in February 1976.[3] We did a larger study

* An oral history interview has also been conducted with Howard Bleich as part of the NLM Medical Informatics Pioneers oral history collection (https://lhncbc.nlm.nih.gov/project/medical-informatics-pioneers), which also carries fascinating histories from other medical informatics luminaries.

Personal collection of Clement J. McDonald.

Barbara and Clem waiting outside the Riley Children's Hospital newborn intensive care unit (NICU), circa January 1979. Clem recalls, "We were smiling because after 23 days of 50% oxygen saturations, intubation and ventilator support, our baby boy was finally turning the corner."

in the Medicine Clinic, which became *The New England Journal of Medicine* paper on the non-perfectability of man—published in December of 1976.[4] Howard reviewed that second paper, and he signed his review—he always does. It was a glowing review. He's quite generous with praise—not a universal characteristic of academics. He was also an associate editor of *The New England Journal*, so his positive review may have been an important factor in the paper's acceptance. Around that time, he also recommended me for membership in a study section at NCHSR [National Center for Health Services Research], a precursor to AHRQ [Agency for Healthcare Research and Quality], and to do something with SCAMC [Symposium on Computer Applications in Medical Care]. Much later, he and Warner Slack also recruited me to join their shop which was very tempting, but I stayed at IU. (Warner is, of course, the researcher whose departure got me to U. of Wisconsin. Also, Warner took over as editor of MD Computing in 1989 after I served as founding editor from '83-'89.) Wonderful connections occur and reoccur.

Source: Personal collection of Clement J. McDonald.

In 1984, Clem, Bill Tierney, and Regenstrief colleagues developed the first PC-based computerized physician order entry system (CPOE), the Medical Gopher. It grew from one workstation in one clinic to more than 1,000 workstations in both inpatient and outpatient settings, into which 100,000 orders per month were placed. The first randomized, controlled trial of hospital-based CPOE was performed on a somewhat later version of this system.[63,64]

JA ***Uh-huh.***

CM Let's see, when did it start? Howard also invited me out to give a talk at his shop in that time frame. That was my first kind of touch with the medical informatics group in Boston.

Well, I had an earlier connection with Octo Barnett.[42,43] He calls me his shortest-term fellow. As an intern at Boston City, I had one six-week outpatient rotation—which meant I had five days per week in the clinic during the day, and only two nights a week of evening duty in the ER and no 24-hour duty. So, I actually had some waking hours when I was not in the hospital and not longing for sleep. In contrast, ward duty meant overnight call duty every other, or every third, night and getting home at 8 or 9 p.m. on nights off after starting at 6 a.m.

At the beginning of the outpatient month, I took sailing lessons on the Charles River. I discovered Octo's shop toward the end of the rotation. It took a while to get an appointment, and when I met with him, I told him, "I want to do a project with you during my internship." And he chuckled. "You're an intern at Boston City? Where are you going to get the time?" "I'll work it out," I told him. Well, the next day I returned to the inpatient service. The door slammed shut, and I didn't see Octo again for 5 years. But, I had lots visits and contact with him and his folks as the years marched on [see picture of Octo Barnett with my fellows on page 40].

There are a lot of these kinds of connections. Richard Friedman [also an internist]—I don't know if you knew him— did train in Octo's shop. Richard traced my path for a time. He ended up at NIH after me. I actually recommended him to the position. He took the position Wisconsin offered to me, and I recommended him there as well.

> We had medical record systems running in real practice environments, but no one noticed.

JA ***Now he's in Hawaii.***

CM I guess I should follow him there!

JA ***So, the greatest accomplishment question comes next.***

CM I don't know how to answer that question. That's not for me to decide, even.

JA ***I'll tell you what Morrie [Collen[44]] said. "McDonald's outstanding contribution was reminders, plus he scientifically evaluated the effects."***

CM Well, we did study things in randomized trials, yeah. I think our group invented both clinical reminders and the use of randomized clinical trials for studying clinical information systems. We certainly were the first to publish such studies beginning in 1976.[3,4,45–47] For more than a decade, our group was responsible for more than a quarter of all of the world's randomized trials of clinical systems per Brian Haynes's systemic reviews,[48,49] and developed quite a reputation for decision support.[50,51] It was also important because doing formal studies gave us access to the most prestigious journals, and that made other things possible. We did our first studies in the outpatient setting but performed lots of randomized trials of computer systems and reminders in the inpatient service[52–61]—the most recent published in *The New England Journal of Medicine* [2004].[62] Siu Hui, PhD, was my biostatistical guru for most of these randomized trials since 1980.

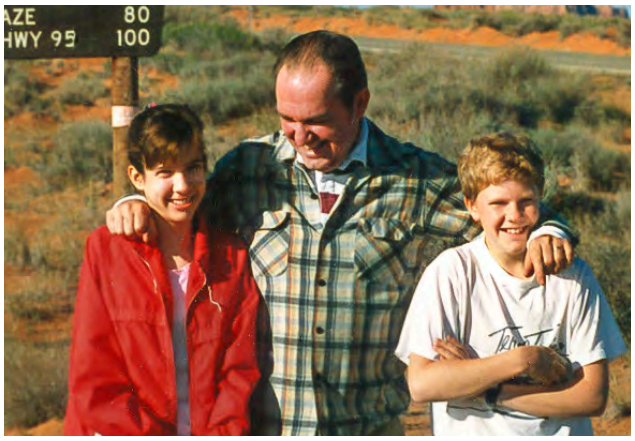
> Except for having kids, there is probably no tickle better than building a system that users love.

DS ***Not in the outpatient setting, though. That was a big deal.***

CM Well, I don't think setting is key. I don't think the process is much different regardless of setting, and we have run trials in both settings.

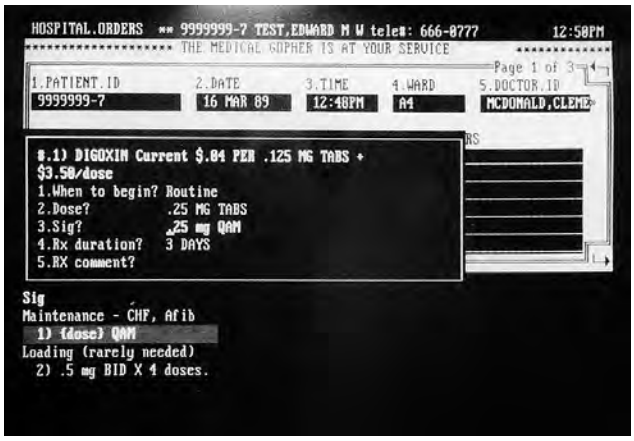
The original reminders were generated as batch processes along with a printed flowsheet and optically read encounter form the night before the clinic visit, as mentioned earlier. Our later studies were performed on the Gopher physician work station developed in 1983[63,64] (the one written in Revelation) and studied the effect of reminders produced while physicians were entering orders or problems into the computer. That was an important step forward, because then we could study the effect of real-time reminders delivered in real time and do it in both the inpatient,[56,62,65–69] and the outpatient,[52–55,61,70] settings, and organized two studies in the Emergency room, one delivered via paper as reminders attached to a printed copy of the patient's medical record abstract[71] and another via the Gopher order entry system that suggested isolating patients with computer evidence of MRSA colonization and produced the highest physician compliance rate – 90% -- of any reminder in our history.[72] Plus. over the course of my career I've been interested in the thought processes -- the ad hoc "rules of thumb, also known as heuristics -- that physicians use to make choices about tests and treatments.[73]

We have had tight connections with the Utah groups, too, for a long, long time. Late in the 1970s, Reed Gardner invited me to visit—probably after



Source: Personal collection of Clement J. McDonald.

Reed Gardner with Carolyn (Clem's daughter) and David (Reed's son) on a trip to Canyonlands, April 1988.



Source: Personal collection of Clement J. McDonald.

Close-up of the Medical Gopher order entry system screen for capturing inpatient medication orders.

the 1976 paper.[4] (A lot of stuff happened after that paper.) And we stayed friends, very good friends, over the years. I had many working visits with them and brought my family along many times for side trips. I also went on camping trips with Reed and some of our kids more than once [see picture on page 25]. Special memories are often attached to trips. Maybe that is because we have enough lazy time on airplanes coming home to burn them in.

I had a special chance to bring my daughter, Carolyn, on a business trip with me to the University of Utah. Reed Gardner and his son took us to Canyonlands in a Jeep over the weekend [see picture on page 25]. What followed was a difficult and twisty drive over irregular boulders on Flint Trail, tipping a four-wheel-drive vehicle more than 45 degrees up, down, and sideways. More like a slow roller coaster than a drive. Then, we hiked 1,200 feet down a steep hiking trail with tight switchbacks and no guard rails, carrying 50-pound backpacks. Reed noted on the way down that what we were walking on was bentonite clay, which is used as drilling mud because it becomes so slippery when wet, but not to worry—no rain in the forecast. When we got to Spanish Bottom along the Colorado River, we set up our tents, ate dinner, and went to bed. The storm hit at midnight—ripped at our tent like an ocean gale attacking a clipper's sail, put two inches of water on the ground, and flooded our tent at 2 a.m. For the rest of the night, I was lying awake waiting for the tent to blow away as the rain howled outside. In the morning, I was very nervous about the hike back up on wet bentonite clay, but it was fine; the bright morning sun had dried most of the trail. "Off-road driving" and "camping" have different meanings to me now. Carolyn was the first one out of the Canyon. We were all quite proud of ourselves.

Source: Personal collection of Clement J. McDonald.

Clem and Bill Tierney with their Oreo-matic cookie dispenser installed outside of Clem's office, circa 1999.

Every time I went to Utah with my family, I would get a car and drive my family around Utah or Wyoming for way too many miles. I wanted to see it all. So, I know Utah as well as many Utahans. Homer Warner wrote about the HELP System in 1971![74] But the first study of its effect came out in 1978.[75] I don't know when they really started using it on the wards. But there were many parallels with our work, and they have continued to do great work since.

Bill Stead[76] and Ed Hammond[76] have also been long-term friends. I remember we were at some meeting in Skyline, Virginia. It was a big meeting of all the honchos, and we were still the little guys in the field. I remember we were fussing over that because we had medical record systems running in real practice environments, but no one noticed.

JA ***Would you consider this [development of reminder system] one of your greatest accomplishments?***

CM I am very proud of that. We were the first to publish formal studies of their effects. But I am just as proud of building one of the very first electronic medical records and possibly the only early system that has continued to run and still is heavily used by clinicians 30 years later. And now it is expanding into the community as the central Indiana health information exchange. Clinicians loved it. They still do. Except for having kids, there is probably no tickle better than building a system that users love.

I also consider the stimulation and development of health informatics standards a very important accomplishment. We wrote a proposal for an electronic clinical reporting standard and presented it at a SCAMC I panel in 1984[14] That draft proposal evolved

into a consensus medical informatics standard (most of which I wrote) published as ASTM 1238-88 in 1988.[15,77] In parallel to the ASTM message, Don Simborg began a more comprehensive standard activity—called HL7—that would serve ADT and most other institutional functions. We talked about avoiding two different approaches. And so I met with Don Simborg's lieutenant, Wes Rishel, at the O'Hare Hilton, for a day and a half. Since HL7 had not yet begun to develop messages for clinical data, we hammered out how they would move the ASTM clinical reporting specification, pretty much verbatim, into HL7. It became part of HL7 chapter 2 and all of chapter 7 observation reporting. We eventually got ASTM and HL7 to agree formally to share each other's work, and I chaired both the ASTM and the HL7 observation reporting message committees and wrote most of the clinical observation content for a time. That HL7 observation message has become pretty important. We estimate from our Indianapolis volumes that at least 30 billion HL7 observation messages are being sent in the US per year today [in 2004]. In 1993, we started thinking about standards for naming and coding measurements and observations. That became LOINC.[9,16–18,78–85] The first version out of LOINC was released in 1995 and since then it has grown immensely.* The seed money and continued support for LOINC came from Regenstrief, but NLM has provided a great deal of ongoing support.

Source: Personal collection of Clement J. McDonald.

National Center for Health Services Research (NCHSR) study section, circa 1979. NCHSR was a precursor to the Agency for Healthcare Research and Quality (AHRQ). Reed Gardner (seated far left); Clem McDonald (seated 2nd from right).

Alerts are not magic. You've got to get the reminder correct enough, at least 33 to 50 **percent specific,** or the recipients will perceive them as the boy crying wolf.

Of course, many others have contributed greatly to medical informatics standards, for example, Stan [Stanley M.] Huff from Intermountain Healthcare. Regenstrief scientist Gunther Schadow, whom I mentored, defined all of the HL7 v3 data types (beautiful) and most of the v3 standard itself, as well as the UCUM** standard for computable units of measure.[20,21] Regenstrief scientist and close colleague Marc Overhage wrote the HL7 v2 standard for clinical trial data. HL7's Arden Syntax[86] is based in a combination of Regenstrief's CARE language (our reminder language)[87] and the Utah

* As of 2016, LOINC codes are provided by most large commercial laboratories in the US. LOINC is required by Federal regulations in the US, and required by government mandate or professional organizations in 28 countries. It has been translated into 12 international languages, including Chinese, Korean, German, French, Spanish, Dutch, and Italian, and 20 dialects. LOINC has collaborative arrangements with IEEE for device codes, with RSNA for radiology report codes, with DICOM for image measurement, and with SNOMED CT for lab answer codes. LOINC has more than 47,000 registered users in 175 countries. [Update from http://loinc.org, Dec 2016.]

** As of 2015, UCUM has been adopted by many large standards organizations including the Institute of Electrical and Electronic Engineers (IEEE) standards for data produced by medical instruments; Health Level Seven, Inc. (HL7) v2, CDA and FHIR for clinical observations; DICOM for imaging studies that report measurements; and the International Organization for Standardization (ISO 11240 — Data Elements and Structures for Unique Identification and Exchange of Units of Measure Information).

Intermountain Healthcare HELP language. Since such standards are essential for getting clinical data into the medical record, they are important in their own right.

And medical records themselves, that's what I started with and was at the core of everything I did. I still think of myself as a computer medical records guy. We certainly were very early in that.[11,12,88,89] The Regenstrief EMR consumed a large portion of our energy and time, both to develop it and to write about it,[10,70,89–98] but it stimulated funding from our hospital bases, provided the tools and data for all of our reminder studies, provided a database for epidemiologic research,[99–103] and provided support for routine clinical trials.[104–106] Indeed our Dean of Research estimated that 80% of the IU human subjects studies used the Regenstrief Medical record at some point in the development of the proposal or the execution of the study.

In addition to the EMR development mentioned earlier, we built the first successful physicians-order-entry work station, the medical Gopher, deployed in the clinics by 1984 and in our hospital by 1989.[63,70] Bill Tierney [in 2015 the CEO of the Regenstrief Institute] was my partner on all of the early Gopher work and was the lead author on many randomized trials of reminders from the Gopher, as well as the only randomized controlled trial of the overall effect of physician order entry on efficiency.[56]

There were some medical record efforts that started earlier but never really took hold.

> Physicians are our friends, not our enemies. That's not how you get people to do things. Enemies harden and stiffen; you don't get anywhere when you consider people as enemies

But the stuff that we started in the early 1970s did take hold and still carries all of the data it collected back to 1972, more than a billion observations now [in 2004],* and is the base for the Indiana Health Information Exchange (IHIE), the largest HIE and a model for the rest of the country.[107–110] Lonnie Blevins, our lead systems developer, developed the programs for IHIE in VAX BASIC on a cluster of VAX-11/780s. Major seed funding for IHIE came from the National Library of Medicine [NLM Contract numbers N01-LM- 4-3410 and N01-LM-6-3546]. Marc Overhage, who was my partner in the early development of this HIE and much of the Gopher order entry system, became IHIE's CEO in 2004 and carried it to new heights.[110]

So, I think my contributions to medical record systems, health information exchanges, reminders, the introduction of RCTs to medical information studies, the development of UCUM, HL7 and LOINC all are strong accomplishments.

DS ***I'm particularly interested in that paper from 1976 you mentioned: "The Non-Perfectability of Man." When you wrote it, did you think it was going to change your career? I mean, when you got that review back from Howard Bleich that must have made you feel good.***

CM That was our second RCT of reminders. We also submitted the first one to *The New England Journal of Medicine*. They rejected it. The Editor, Franz

Source: Personal collection of Clement J. McDonald.

Barbara teaching Christopher to play the piano, circa 1981.

* By 2016, the RMRS software inside of the Indiana Health Information Exchange carried nearly 6 billion items of clinical information, for 12 million individuals. [Update from http://www.ihie.org/]

Ingelfinger, sent a really nice page and a half letter—a very encouraging letter. He said, "Well, we can't publish it because of this and that, but this looks like really interesting work that you ought to pursue," and he took a personal interest. I haven't gotten such a letter from an editor since. Ingelfinger was famous for that.

Our first reminder study, after being rejected by *The New England Journal of Medicine*, was accepted by the *Annals of Internal Medicine* and published in February of 1976.[3] *The New England Journal of Medicine* accepted our second reminder study and published it in December 1976.[4] We published the largest RCT of reminders in 1984,[46] a two year study of 1,200 reminder rules applied to 12,500 patients via more than 50,000 reminders, all of which were delivered on printed paper reports (most of which, interestingly, had a similar sized effect on provider behavior as those delivered through the gopher order entry work station.

We now have reliable power systems, redundant disc drives, adequate computer speed, plenty of memory, and cheap terminals, so we can put them everywhere.

I don't know what I was thinking back then. I was hoping to do something really useful, and that's what kept me working at the Institute until 11 o'clock at night in the early days. If you were going to work late, you had to stay at work, because telephone links were horrible and you could not carry the computer home. It filled part of a room. The only choice was to use a terminal while sitting in the Regenstrief Institute. My wife, Barbara, was very accepting of my extreme hours, then and always, despite the fact she was caring for three babies under age five around that time. She even learned a bit of programming as a sharing thing.

I always worried about how to present the results to reviewers. We would get letters like, "But what's the point? No one else has anything like this." One reviewer raged at us about the fact that humans think, computers don't, when we said the computer "knew" the facts about the patient, and, of course, he did not like the paper. The lesson was: Never say, "the computer knows," even as an analogy. The reviewers can go off on the most picayune issues.

So, yeah, it did, it opened up many doors.

DS ***Right. So you got to go to Utah, Boston, give talks and things like that.***

CM Yeah.

DS ***That was interesting that you say you struggled with the presentation of the data, and you had the reviews.***

CM Well, when you'd write, you'd try to put the verbal fences up to head off negative conclusions and avoid offending biases or pushing the reviewers' hot buttons.

DS ***I know. So, one of the things I think is the most interesting finding in it was that the alert didn't educate the humans. When you were building the system and putting it in, was that one of the things you wanted to show?***

CM Let me think. Did I have prior biases? I am not sure, but the results did not surprise me. The things we reminded about were not new or controversial recommendations, and the rules behind them were relatively simple.[52–54,61] Our efforts to guide complex management decisions with computer reminders were generally unsuccessful.[61,111,112] I think going in, we had the impression that the problem really wasn't ignorance, it was information overload. Indeed, we made a big point of that in the 1976 paper.

DS ***Because, you know, I don't think that message is still through to people. People still think that the reason physicians override so many alerts is because they've learned all that, and they've moved on.***

CM The other thing about alerts is that the guys that write them are often offended when physicians ignore them. They don't want to consider that the problem might reside with their rules rather than the recipients. Physicians reject or ignore alerts, reminders for many good reasons: crumby rules, crumby computer systems, and incomplete EMR data—for example, reminders about flu shots based only on

shots received in your institution that ignore the shots given at pharmacies or physician's offices. Alerts are not magic. As I was saying yesterday, reminders can be a low-grade ore. You've got to get the reminder correct enough, at least 33 to 50 percent specific, or the recipients will perceive them as the boy crying wolf. Yet system developers sometimes decide that doctors are the enemies.

We work very hard to remember that the physicians are our friends and our colleagues, not our enemies. That's not how you get people to do things. Enemies harden and stiffen; you don't get anywhere when you consider people as enemies.

You've got two components to make a reminder rule good. One is having the right, timely and consistently available data in the computer, and the other is having the right rules. And there can be problems with both. The computer is not typically going to have all the information that a physician has, depending on the rule in question. On the other hand, some decision rules lack evidential backing, and developers guess or opine and create rules whose reminders physicians might be right to ignore.

You can find clinical statements that are rule-like but are not decidable.[113] Many so-called guidelines are sometimes just polished whimsy; the "experts at the airport" thing. So, one federal organization was spending in the order of $60,000 for experts at the airport, and the rules were sometimes scientific and sometimes just pure opinion. Some of them were agreements between experts with different hammers, and they would all support the use of each other's hammer. I think the pain guideline accepted every approach to pain treatment so that all of the participating experts would be happy. Every expert got their stuff recommended.

> We created LOINC to solve the code problem to make HL7 work.

This guy Ian Stiell, in Ottawa, spent $60,000 capturing findings for 1,000 patients with ankle pain after trauma and decided empirically what the rules for getting an ankle X-rayed should be.[114,115] Well, there you have something. The field is really short of such good empirically based rules, though. Cardiologists have got a lot of good ones. ACE inhibitors, LDL level, use statins. A lot of prevention rules, some cancer detection, and immunization rules are based on evidence and come with explicit thresholds so they are decidable and easy to implement. And after that, it gets real hard. None of Regenstrief's sophisticated therapeutic guidance rules ever worked.

> LOINC serves as the question (or **a field name or a** variable) to set the context for the answer.

Source: Personal collection of Clement J. McDonald.

Carolyn, Chris, and Clem III enjoying a brand new DeLorian, like in the movie Back to the Future, when a good friend drove it over just so they could sit in it, circa 1981.

Source: Personal collection of Clement J. McDonald.

Much work was needed to upgrade the fire truck to DeLorian standards. Carolyn, Clem III, and Christopher all contributing, circa 1981.

DS ***In the whole world, huh? Are these the most recent papers you're discussing, or over the history?***

CM We haven't published some of this stuff.

DS ***The stuff that doesn't work? It's hard to get published. For a time it was even hard to get the stuff that does work published.***

CM The best example of very sophisticated rules that really work are the antibiotic assistant rules at Intermountain Healthcare. But those rules require very heavy investment in data gathering and rule maintenance.

DS ***Some of these reminder papers that we're talking about now were published 25 years ago.***

CM It has actually been almost 30 years since our 1976 papers.

DS ***That's too much for me to figure out—yeah. Why has it taken so long for people to adopt these systems, with the decision support? People have adopted some computerized medical records, but very few people have taken up the decision support part.***

CM Well, they have to build the EHR [electronic health record] first.

DS ***Why has that [building EHRs] been so slow?***

CM Because it's hard. It is very hard. At the beginning, we were hitting our heads against the wall and fighting and struggling and begging to get data that clinicians desperately wanted to be in the computer; so they could get to it easily. Yeah, the docs want it, need it, but someone else changes something about the input for a billing reason or based on a matter of taste regarding the format of a clinical report, and that breaks all of the spit and bailing wire interfaces we built before HL7. No attention to the importance of getting the data to the computer for easy clinical access. So it's just plain hard. But it has gotten easier.

DS ***What's made it easier?***

CM Well, the technology's gotten a lot better. We now have technology we can work with. We now have reliable power systems, redundant disc drives, adequate computer speed, plenty of memory, and cheap terminals, so we can put them everywhere. No such capabilities were available in the early days. I think the adoption of HL7 messaging has been a godsend. We get good HL7 messages today. In 1991 and 1992, we had these vendors come in, and they'd say, "Yeah, we support HL7, and we support MEDIX." Well, MEDIX never existed. So once they'd say that, I'd know, "You don't support anything." It was just kind of a mess. From about 1992 to '93, we started seeing pretty decent HL7 messages from most vendors. Within an organization, where everyone uses the same codes, HL7 works well. Across organizations, you've got the code problem.

Get to the point where you can prove your point.

DS ***Is that when you started the idea for LOINC?***

CM We created LOINC[9,16,116,117] to solve the code problem and to make HL7 work.

DS ***Between organizations, or just HL7 made to work better within an organization?***

CM Standard codes are not needed as much when you're within an organization, because the organization already tends to unify codes for their business purposes, though LOINC, well-implemented, would help them too. The problem with messages from external sources was that you would get an HL7 message, but you couldn't automatically file the data it contained because you don't know the meaning of the code that labeled the observations they were sending without lots of mapping work.

DS ***Yes.***

CM So the big remaining challenge is in the codes.

DS ***So at the time, SNOMED [Systematized Nomenclature of Medicine] was trying to do this kind of thing. How come you made your own LOINC thing?***

CM SNOMED was not doing the same thing with lab codes when we started in 1994. They had codes for many of the analytes and many of the specimens, but few full names or codes for lab tests.

* SNOMED and LOINC came to a solid and fair agreement for spheres of influence in 2013 and have had a wonderful collaboration ever since. [Update from Clem McDonald, Feb 2016.]

DS *I hear from some of my sources that there's still a little disagreement between you and the SNOMED people about the way things are.*

CM While SNOMED was still part of CAP, we agreed to use their more atomic concepts to construct our codes and they could incorporate the parts of our codes—analyte, method, properties—that they did not have as atomic concepts. They did take the parts from about 16,000 LOINC codes back then. We'd do the questions; they would do the answers. We wrote a formal agreement. It's published in the agreement that we would not make up codes for atomic things, and they would not make up codes for lab tests. We defined a lab test as anything that had at least an analyte and a specimen together as one concept. SNOMED had a code for glucose and a code for serum. But they generally did not have codes for an analyte and a specimen together, as needed to label an observation. At least not when we made the agreement.

Source: Personal collection of Clement J. McDonald.

Great Smoky Mountains, spring 1982: Carolyn, Clem III, Christopher, and Clem.

And then they started making up such codes—despite the agreement. They had to because of their agreement with the NHS [National Health Service]. But we only found out later.*

Most information is packaged as a "question" and an answer. You need the question to give context to the answer. If someone just sent a whole bunch of answers—it would be like giving you baseball scores, 1 to 3, 4 to 5, 6 to 7. You need some context: what team had what score? If I say this field is the discharge diagnosis code, and the code is an ICD-9 [International Classification of Diseases, published by the World Health Organization (WHO)] code for breast cancer, that's one thing. If the field in question carries the reason for doing a mammogram, it's another. Because what the MD probably said in the reason for the study was "rule out breast cancer" and the ICD coding rules require converting "rule out diagnosis X" to "diagnosis X," it ends up being the code for just "breast cancer." You need some of this context to know. Or patient weight: Is that the patient's statement of the weight, or is it the measured weight, or is it somebody's estimate of the weight? LOINC serves as the question (or a field name or a variable) to set the context for the answer.

DS *So how long do you think it'll be before more organizations start adapting and using the LOINC codes and start recording this stuff?*

CM I'm not good at predictions. Five years ago, I told my Chairman of Medicine that voice understanding is the answer to collecting physician notes. It was 98 percent accurate. I said, "I can guarantee you, in two years, we'll have 50 percent of the physicians using it." We did a study.[118] We couldn't even get the six informatics researchers who volunteered for the study to keep using it for the whole study. And it is "perfect"— but just not perfect enough. So I think it's really hard to say.

But there is a fair amount of use of LOINC. It has been translated into Chinese. The Chinese government published a 3,000-page book, as big as Harrison's [Principles of Internal Medicine textbook], carrying all of the LOINC codes in Chinese. LOINC has been adopted by both Canada and Germany as their national standard.

DS *Wow. Good.*

CM And I think Quest, and Lab Corps, and ARUP can send out LOINC in their lab messages now.

DS *That's good. That'll help a lot.*

* SNOMED and LOINC came to a solid and fair agreement for spheres of influence in 2013 and have had a wonderful collaboration ever since. [Update from Clem McDonald, Feb 2016.]

CM Boston Partners uses it. The National Committee for Quality Assurance group will be requiring it for reporting quality in HEDIS [the Healthcare Effectiveness Data and Information Set]. We use it. Intermountain Healthcare uses it. Columbia uses it. Insurance payers ask their lab companies for it. We hear of it from their consultants. They'll call and ask, "What's this LOINC thing, because Blue Cross says we have to get all our lab stuff labeled with it."

DS ***I'm sure they are.***

CM So I don't know what the timeframe will be. It will be one of these biologic S-shaped growth curves.

You can ask the same question about SNOMED.[119] I think they have an even tougher challenge because so much of the content that could or should be coded in SNOMED is now recorded as free text, and people have a hard time giving up the freedom of narrative text.

DS ***In informatics, there has been a long history of academic developers, and them trying to sell their systems. We say we're trying to do it, I suppose, so more people can have it. We always think, privately, we're going to get rich, too. I don't know if you ever think that.***

CM I never thought that.

DS ***You don't think that?! You're smarter than us?!***

CM Maybe not at the beginning, but I came to think that it is not a good idea to mix your businesses. That is, if you're not an expert at it, don't do it. So, I decided at some point to stick to the path where the principal goal is to learn stuff and to demonstrate stuff. If you are going to start a business, concentrate all of your energy on that and drop the academics and vice versa. Remember, it is a lot easier to develop, implement, and demonstrate something at one place than to make a product that will run everywhere. *The Mythical Man-Month*[120] says it all [a book of essays on software engineering and project management by Fred Brooks, whose central theme is that "adding manpower to a late software project makes it later"].

DS ***Yeah, I've heard that.***

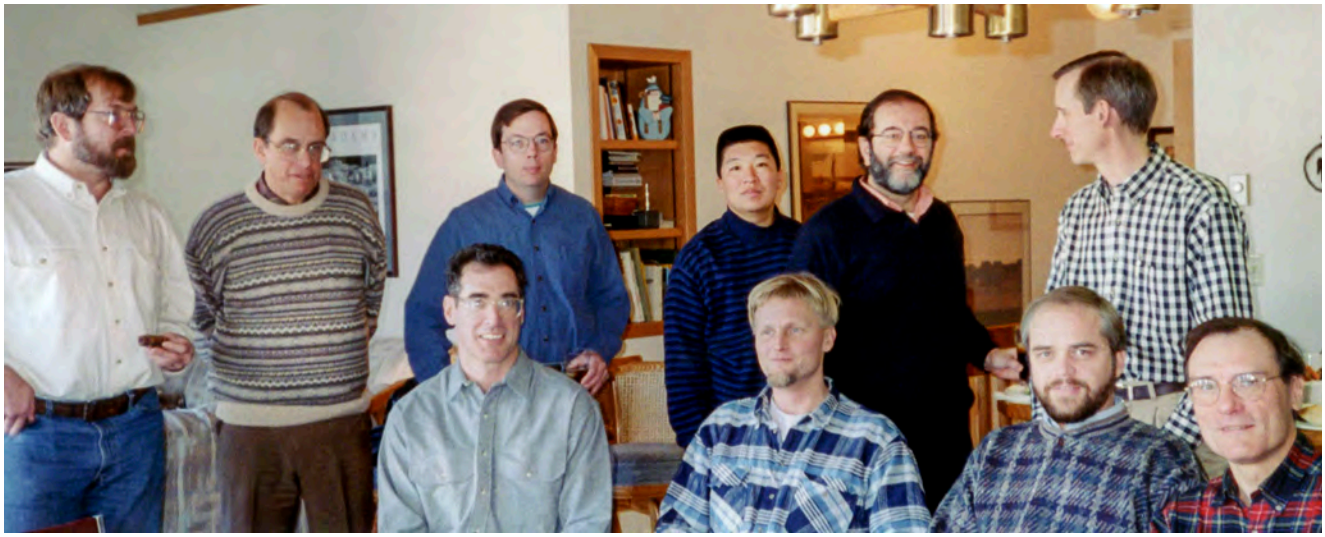
CM It takes one unit of effort to make something work at one institution and three units to get it working at a second place, and twelve units of effort to get it robust enough to work anyplace. We weren't thinking our goal was to sell products, but to sell ideas. But we were sometimes pressed by the board members of the Institute, by—"Well, if this is that good, why don't you make it commercial?" So there is sort of this business theory of life. But it's a distraction. What I've always told my folks here—fellows and all—is that the goal is to do the least amount of work to get to the point where you can prove your point; get something working in a real setting and conclude something. Do as much as you can to test the idea with the least work. You want to show such and such, but don't start out building the whole infrastructure. If you can take a shortcut to prove that your idea works, do that; then you know it's worth building the infrastructure underneath. Or else take something where there is an infrastructure you can tap into, and build on that.

I like the idea of so-called extreme programming. My interpretation of extreme programming is that you never, ever develop anything but prototypes, which you then continuously improve. Of course, these have to be robust prototypes not crumbly ones. The old waterfall strategy of design it all and then develop does not work because users who specify the design do not know what they really want until they begin to use it.

DS ***And hope someone will come along and make the product behind you?***

Source: Personal collection of Clement J. McDonald.

Carolyn, Clem III, and Christopher, Yellowstone, 1985. Dad is the photographer and hoping the bison stays happy.



Source: Personal collection of Clement J. McDonald.

Clinical LOINC meeting in Big Sky, Montana, January 11-14, 1997. January 12th was a record cold -40 degrees F at Rainbow Ranch on US 191. Standing (left to right): Stan Huff, MD (chair of the Clinical LOINC Committee), Karl Hammermeister, MD, Bill Francis, Blaine Takesue, MD; Angelo Rosi Mori, PhD, Dean Bidgood, MD. Seated (left to right): Dan Pollock, MD, Anders Thurin, MD, Bruce Brey, MD, and Alen Golikowski, MD.

CM That would be okay, but the place you developed it in could continue to use it and expect continued improvement. In some universe, I would hope that more hospitals will be building software just for themselves.

DS ***Really?!***

CM Uh-huh.

DS ***It seems like it's going the other way, to me.***

CM Oh, it definitely is.

DS ***And that's worrying me.***

CM Yeah, the same with me. But I think if you look at the money they're spending, hospitals have very large budgets—. In this town, I think we have at least three hospitals that have budgets that are presently bigger than almost all the current medical software companies.

DS ***Is that right?!***

CM SMS's was a billion dollars when it was the biggest of all.

DS ***A billion dollars of revenue, you mean?***

CM Yes. The biggest hospital system in Indianapolis has a revenue stream close to 2 billion. Partners HealthCare, in Boston, is probably 5 billion. So hospitals are hostages to companies that aren't as big as them. The reason I'm saying this is because now, we should be able to build more with less because the tools are getting better and better. You know, we should not have to build it from the ground up. To the degree that an organization could start with existing open source code or commercial widgets and frameworks, it might be easier than implementing a commercial system.

DS ***Are there enough people that know how to do this, to help all these hospitals?***

CM Probably not. I think it doesn't really matter what is possible. It all depends on the belief structures, and they are now all going the other direction. There is a herd mentality among hospital CEOs and CIOs. A non-herd CIO at UCLA, with his hand-built stuff, was saving the institution tons of bucks, and of course they respond with, "Oh, you don't have this or that!" Or, "You couldn't possibly do X or Y." Well, big corporate developers didn't and couldn't, either.

And if you look at where they're spending their money, hospitals are spending money in customization to make the commercial system fit their needs. There is no advantage of scale or permanence to these customizations. So we might have the wrong model. I think that as the software chunks you can build on get bigger, the hospitals, big institutions, should be internalizing. And then they tailor their own, or they just keep modifying it so it's always tailored well. And there is the thing about managing transitions. What happens to these big commercial systems? They don't last forever, either. Then the institution may have

more pain if they don't have any internal expertise, which dissipates if they outsource everything.

DS ***And then once they get a big installed base, they can't change it. At least at your hospital, you can change it.***

CM Yeah. So I think that in the long run, if you look at the bigger trends, those hospitals should be thinking about doing more development with bigger tools—fifth-generation, whatever, big pieces that you can join together. Because you look at the economics of it, it doesn't work out the way people say. And the happiness level of physicians and nurses never works out the way they say.

DS ***I think we had so many failures earlier, and they say, "Well, if I buy a system, it'll only do 70 percent of what I want, but I'm sure of getting 70 percent. I probably won't fail."***

CM I'm not saying there are not going to be failures, but the rule has become, "You simply have to buy."

DS ***Can't afford that failure.***

CM Well, the other solution is to figure a way to do things in smaller bites—gentle implementation—because no one can afford the failures. Big commercial systems may not fail catastrophically, but they may fail continuously by not satisfying needs. So the open source part is sort of like a spin on the same thing. That is one thread of how to do it; if institutions could actually share more easily, they might be able to build on top of others' work.

> The biologic reality is that humans are all mortal. It's a bad situation when we blame all deaths on errors. We're going to end up spending so much money meticulously measuring the steep biologic decline at the end of life and investing increasing amounts on futile care.

DS ***We haven't shared well.***

CM Yes, because everything's so specific and tied to a specific underpinning. With a little more standardization, the ability to plug and connect things should get better, but we're not there yet.

DS ***Who pays for LOINC?***

CM Well, we get funding from the NLM, we get funding from the Regenstrief Institute, we get a little bit of funding from the CDC, and so I guess we're getting paid, too.

DS ***A little bit.***

CM The same way. But we're not selling software; we're not selling codes—it's all free. I don't have any objections to people making money—it's America, you know. But I do have objection to 501(c)(3) organizations that are tax exempt making huge amounts of money.

DS ***Speaking of free things, you know, there is a lot lately about open source software. And I've read papers coming out of your group that you're moving to open source. I've heard someone say things like, "We tried open source a long time ago, and it didn't really work that well." He didn't feel like it was a total success. Is LOINC work an open source? Like when you said the Chinese—I mean, they must have translated them—you didn't translate them to Chinese, did you?***

CM Right.

Source: Personal collection of Clement J. McDonald.

Clem's dad, Clement J. McDonald, Sr., circa 1995.

DS ***It was someone from China. Someone else's doing.***

CM Yes, and LOINC keeps the copyright and distributes free. That's just how we're trying to do it, so that it really has some benefits.

DS ***Are other people making LOINC codes, or is it really that all the new codes are coming out of you?***

CM Only LOINC central at Regenstrief can make new LOINC codes. That is the only possible model.

DS ***So you make them.***

CM We have to. If they give us good submissions, we can turn them into formal LOINC terms and assign codes quickly. The whole goal is to gently nudge lab and clinical systems toward a more common way of describing their observations. The current base state would not get us there. We have to check each submission to be sure they don't duplicate existing content and that the terms come with good definitions, sample values, and answer lists (if they are categorical, etc.) and that tests that are similar follow similar naming rules. Letting everyone create their own codes and defining the meanings and names in different ways or not defining them at all will not work. That is the current state of the world that we are trying to change.

But the challenge is that LOINC has this huge scope. Lab LOINC is constrained. Clinical LOINC is not, and people say, "Well, Clinical LOINC is incomplete." Well, duh! We should not be comparing Lab LOINC with Clinical LOINC, but instead with EKG LOINC, ventilator machine LOINC, or nursing assessment LOINC, because those are also spaces that have "finite" boundaries.

Source: Personal collection of Clement J. McDonald.

Clem and Barbara's children Clem III, Carolyn, and Christopher, circa 1988.

DS ***Were you working in all those spaces?***

CM There is some work in all those spaces.

DS ***I wasn't aware of that.***

CM Yeah, there is a pretty good set of LOINC codes for OB ultrasound, cardiac echoes, EKGs, and vitals. There are a number of nursing survey instruments.

DS ***Is that what you're working on now?***

CM We have been all along, but it really depends on volunteers and an expert group that knows what terms are needed. You get a group or an organization that wants to organize a given content and has adequate knowledge of that content. Then LOINC takes it in.

DS ***You've already mentioned several times when you had some disagreements with major organizations. It's not like you're fighting little people.***

CM I've actually had fun over the years, finding flaws in scientific reports and fighting for corrections. I think I had four letters to the editor that got attention about problems I uncovered. There was a paper by the editor of a major gastroenterology text that claimed that steroids didn't cause bleeding. It sure seemed like I had patients who got gastric trouble from steroids. So I looked up all of the papers cited in his paper. It turned out that the control group to which they compared steroid-treated groups included people on azathioprine and aspirin—things that knock out platelets and also cause bleeding. And in fact, if you threw those bad "controls" out, the conclusion was

opposite to what was reported in *The New England Journal* paper.[121] The author actually sent me a nice letter.

And then there was a study about HIV that claimed there was zero risk of infection from close household and spousal contacts who were HIV positive, but the sample size was small. So their zero result had confidence limits of something like a zero to 9.2 percent rate of infection, hardly a safe margin.[122] *The New York Times* actually interviewed me on that one. I also wrote a paper with a statistician from Purdue University arguing that regression to the mean accounted for most of the improvements attributed to use of placebo.[123]

DS ***We always joke in our group that every physician-order-entry paper, every electronic medical record paper, begins with, "In the 'Crossing the Chasm Report,'" and then that proves everything else they say. I know you've had a little disagreement with the way they've addressed some of their data analysis, and I wondered if you could—.***

Source: Personal collection of Clement J. McDonald.

Clem (right) celebrating his 1992 Indiana University promotion to rank of Distinguished Professor of Medicine, with his dad, Clement J. McDonald, Sr.

CM My disappointment is with the IOM [Institute of Medicine] 1999 error report.[124] Its scientific sloppiness and headline seeking should have been an embarrassment to them. The paper on which they based their conclusions did not make the same assertion that the IOM report made, and at least two of the co-authors of that paper criticized or rejected the conclusion of the IOM report entirely. However, I have no disagreement with the IOM's "Crossing the Chasm" report.[125]

DS***Yeah. "To Err Is Human" is the one— [unclear] 98,000 deaths.***

CM That's what sticks in my craw. The 98,000 figure did not make sense. We would be tripping over that many bodies. I groused about it for about six months, and then somebody said, "Well, why don't you see if you can get the data to challenge it?" So I tried and did.

The key paper in the IOM report[124] took a subset of cases based on a number of criteria, to find a high-risk subset. That subset was about 7,000 out of the 32,000 patient cases. And in that subset, they reported death rates for the one-seventh who had adverse events, some of which they attributed to errors. They reported nothing about the other six-sevenths. When we looked at the whole data set (about 7,000 high-risk patients), the death rate was the same (about 13 percent) in both groups.[126,127]

The biologic reality is that humans are all mortal. It's a bad situation when we blame all deaths on errors. The scariest thing about the errors report is that we're going to end up spending so much money meticulously measuring the steep biologic decline at the end of life and investing increasing amounts on futile care. We will engage in technical medicine to the nth degree, for no useful purpose. We don't have enough nurses on the wards. We've got people who can't get their blood pressure medicines. And they're going to make this huge investment in making process so perfect that we have no resources for the basics.

I was on Katie Couric's show, talking about the flaws in the error report. That was the scariest thing I've ever done.

DS ***Why was that scary? I didn't even know you were on!***

CM Mostly, I have very few fears.

DS ***This is 50 million people, though, isn't it? Or was it her?***

CM There is no freedom to explain or defend. I wanted to show a little slide that would explain— "No, you can't do that." And you're completely at their mercy. You're watching the clock, and you're in a cattle chute: "Okay, you're on!" Everything starts up.

DS ***Oh, man!***

CM I told them I would not do an across-the-table argument with anybody. It's just not gracious, in our field, to say, "You dumbhead!" across a table. I said I wouldn't do that. They agreed. But then, they put Lucian Leape, who led the error report, on, but remotely. They told me about that 30 seconds before I went on. He was gracious, so it was okay. And I couldn't articulate the issue. It's too subtle. Many said I was lucky because Katie was kind and did not shred me.

DS ***Yeah, I was going to say, it's a difficult point to make in the 30 seconds you get with Katie Couric. I can imagine.***

The last thing I was going to say is that one of my favorite papers of yours is the Canopy Computing paper.[128] I've been hearing you talk about these papers, and you said before that you sell ideas. I can just see you sitting around thinking, "I'm going to tell someone about this idea," and I was just wondering, what prompted that Canopy Computing paper, where you just talk about the jungle, and the people swinging from the trees and stuff?

CM Well, it does describe the model we would like to achieve for medical data access. All of the patient data needed for clinical care is available in various medical records and if these individual sources could be accessed without boundaries, like the arboreal canopy, it would improve and facilitate both care and research. I guess I should keep better notes about idea origins. In South America, there are a couple of places where there are walkways between the trees—up in the canopy. I think I saw some TV show about life up there. I like to find some colorful thing on which to pivot a paper, though they don't always work.

DS ***The Canopy Computing was pretty cool. I'll have to give you that. "The Non-perfectability of Man" was a pretty colorful thing.***

CM There have been a number I've tried that haven't worked.

Let's go back to the question about why implementing electronic medical record systems is hard and a slow-going process. It's in the wiring. All this work is in the wiring, and sometimes, it's human wiring. They have to know how to push this button and all that kind of stuff. And there are a gazillion wires to link up. It's the difference between a heart transplant and a brain transplant.

DS ***Hm. Not many wires in a heart, I guess.***

CM Not many—there are four connections. The brain has gazillions and gazillions. We can insist all we want, "We have to do this tomorrow." It's going to happen slowly. I don't think there is anything anybody can do to change it. No, let me take that back. Faster standardization could change it. An important effort is compliance testing against existing message and code standards and then, some kind of inducement that people really use the standards, especially the codes that identify observations. If we could get more usage of standard codes in there, we'd do better,

Courtesy Sandy Poremba, Regenstrief Institute.

Marc Overhage, circa 2003. Clem recalls "He was a Regenstrief informatics fellow from 1990-'92, and became a national leader in medical informatics. He was my partner on many studies and the expansion of the Regenstrief Medical Record to the whole State of Indiana (IHIE) and he became a CEO of that effort.

Source: Personal collection of Clement J. McDonald.

On March 8, 2004, U.S. Senator Bill Frist, MD (R-TN), a physician, invited Clem and other policymakers and physicians, to a dinner and discussion hosted at the Senate Office Building to discuss strategies to spread the use of electronic medical records. Photo includes: Newt Gingrich (far left, who founded the Center for Health Transformation in 2003), Senator Bill Frist (red tie), Hillary Rodham Clinton, Ralph A. Korpman, MD, Tim Johnson, MD (medical news contributor for ABC News), and Clem McDonald (far right). Clem recalls that Mark McClellan, MD, PhD (Administrator for the Centers for Medicare and Medicaid Services in the United States Department of Health and Human Services) was also at the event although not in this photo.

though I don't think we should try to code most of the physician's current narrative.

DS ***Do you think we can screw anything up by trying to push people to go faster?***

CM Oh, yeah! We can set the effort back for years.

DS ***That's what I was thinking.***

CM This whole immediate Federal effort to automate healthcare data in mid-2004 may be much ado about nothing. It doesn't matter what they're doing now, because in two months, things will be different. I mean, no matter who is elected.

DS ***They're going to be different.***

CM Yeah, there'll be a new Secretary of Health. There'll be new economic realities. There'll be new something.

DS ***Some move back to reasonableness?***

CM Yeah. Tommy Thompson is very, very charming, and very articulate. I was on a panel with him last March. Somebody asked him a question. "How come [some] report hasn't gotten delivered by this time?" And he started saying, "You know I've got 80,000 employees. I don't have the foggiest idea, but I'll get back with you." I mean, that was a nice, honest answer. But at a later meeting about health IT he said, "We're going to do this (meaning implementing medical records) by June (8 months in the future)." Though at that time, HHS [the Department of Health

and Human Services], which he headed, had not finished the National Patient Identifier (NPI) project after *eight years of effort.* And the NPI is only one of the components EMRs need to be successful. If we had a national patient ID, Lordy, Lordy, half of the problems of this connecting data would be solved. You've got people waiting in a waiting room a half hour to register; it's because they don't have a patient ID that anyone else knows.

DS ***I forgot about your disagreements with the patient ID folks. Why couldn't AMIA even agree that we should have a patient ID?***

Source: Personal collection of Clement J. McDonald.

Octo Barnett, MD, in center surrounded by Regenstrief Medical Informatics Fellows at AMIA meeting, from left to right: Paul Biondich, MD, Phil Kroth, MD, J.T. Finnell, MD, and Burke Mamlin, MD. circa 2004.

CM Well AMIA did agree that we should get a patient ID some years ago.[129] But Congress forbade it. Political forces are such that we are not going to get a patient ID. So our real trick is to shut up about it so we don't get the Social Security number abolished as well. We can't use Social Security by itself to link the same patient records from different sources. It is not sufficiently accurate—typos and spousal mix-ups between the guarantor and the patient at registration—but without it, the matching is very, very tenuous in big populations.[130]

DS ***But without it, you can't do it.***

CM Yes, that is so. Without a solid ID you can only get close. You're within 5 percent. It would be okay for statistical research purposes, but not for patient care, when you're going to give the wrong patient a dose of something based on someone else's data. But with Social Security and the other keys (for example, birth date, name), you can do very well.

DS ***So you really want to make sure we don't lose the Social Security number.***

CM Yeah, but I think it's still unfortunate and irrational that we don't have a solid universal patient ID—do it right. They have it in England. Doesn't seem to hurt anything. They have a universal ID in Canada, doesn't seem to hurt anything. They've had it in the DOD [Department of Defense] and the VA [Department of Veterans Affairs] for 50 years—that hasn't hurt anything. But that's the peculiarity of our system.

DS ***All right. Well, I'll turn it back over to Joan to finish up.***

JA ***Okay. Well, let's see, we have five minutes, and what I wanted to cover was training and education, because we're in the middle of all these wonderful fellows you have around you, and I wanted to get at what started that, the first ones, what's that like? But then we also need to talk about your role in professional organizations and the role of research in clinical systems evaluation, because I understand that's very important to you. So, I'm thinking that maybe we should pick one of those, and then if you can give me a half-hour during MedInfo sometime, we can finish the rest. Maybe we should start by talking about the fellowship program and training and what you've done over the years with that.***

CM Okay. Well, basically, for most of my career, Regenstrief had an ad hoc fellowship. When we had a candidate who wanted to come be a fellow, we made him a fellow—we didn't have much formality to it. We had about 18 before we got a formal NLM fellowship grant in 1976.

DS ***An informatics fellow, you mean?***

CM Right. So Greg Wilson, who now [in 2004] is the Head of the Public Health Department in the State of Indiana, was the first one. Bill Tierney was an informatics fellow—he started in 1980. Dave DeBrota, a wunderkind, started in 1986. Marc Overhage was a fellow from 1990-'92. Gunther Schadow, of HL7 and UCUM fame, began around 1996. Some others pre-NLM fellowship funding were Doug Martin (who worked in the VA system), Dave Smith, Paul Dexter,

and Jeff Suico, to name a few. We had even more after we started getting NLM funding.* A total of maybe more than 30, many of whom went on to academic careers.

DS ***You've picked some good ones, haven't you?***

CM Yes, very good ones, but they picked us. We had people come to us. I think Howard Bleich influenced my thinking. "We don't want fellowships," he said in early years, "because they just distract." He later changed his mind about that. If they really wanted to do informatics and research—and I never was certain this was something that would be good for someone, versus going into a high-paying specialty—but if they really wanted to do it, then come on down. And I had a couple of students come by, and I sent many people away. "Oh, I'd like to be a fellow." And then I say, "Well, why do you want to do that?" He would say, "Well, I hate medicine." (Brrrttt! [buzzing sound to indicate disqualified]) Or, "If I could do medicine and computers, I'll be twice as rich!" (Brrrttt!) I would tell them life is just a train ride. You've got to enjoy the ride. Don't count on getting any big special reward at the end of the ride.

JA ***When was that, that you had your first one?***

CM It was probably '80 or something like that.

DS ***So soon after you got here.***

CM Well, I got here in 1972. I was pretty much alone then, so it wasn't till after 1976. Bill Tierney's really important in this discussion. Joe Mamlin picked Bill for the "informatics" fellowship and Joe is always right. Bill was my partner or the lead in our randomized trials for a long time. He also set up the

---

* The following medical informatics fellows (and one medical resident) assumed full time academic positions after completing their programs. It is not a comprehensive list. It does not include those who went into industry or government positions and our records are imperfect; so we may also have left out some trainees with current academic careers and we apologize in advance for any such omissions. (in alphabetical order; provided by Clem McDonald, January 2017):

- Paul Biondich, MD, Associate Professor of Pediatrics at the Indiana University (IU) School of Medicine (SoM) and Director of the Global Health Informatics program at the Regenstrief Institute, Inc. In 2016 Paul Biondich and Burke Mamlin won the 2016 Donald A.B. Lindberg Award for Innovation in Informatics for developing Open MRS (http://openmrs.org/about/) and distributing it to health care systems in under-developed countries.
- Paul Dexter, MD, Associate Professor of Clinical Medicine and Assistant Clinical Professor at Indiana University, an investigator at Regenstrief, and also a part-time hospitalist, chief medical information officer at Eskenazi Health Services (previously Wishard Hospital), interim chief research information officer for the Indiana Clinical and Translational Sciences Institute (CTSI), and the medical director of ResNet, a primary care research network managed by the Indiana CTSI.
- John T. Finnell, MD, Associate Professor of Emergency Medicine at the IU SoM and a Research Scientist at Regenstrief.
- Shaun Grannis, MD, Associate Professor of Family Medicine, at IU SoM and the Interim Director of the Regenstrief Center for Biomedical Informatics.
- Abel N. Kho, MD, Associate Professor of Medicine and Director of the Center for Health Information Partnerships at Northwestern University Feinberg School of Medicine.
- Marc Kohli MD, Assistant Professor of Radiology, and Director of Clinical Informatics at UCSF School of Medicine.
- Philip J. Kroth, MD, Associate Professor of Medicine at the University of New Mexico (UNM), Director of Biomedical Informatics Research, Training and Scholarship, and Chief Medical Information Officer of UNM Hospitals.
- Burke W. Mamlin, MD, Associate Clinical Professor of Medicine at the IU SoM and a Research Scientist at Regenstrief.
- Douglas Martin MD, Professor of Clinical Medicine at IU SoM.
- J. Marc Overhage, MD, PhD, Emeritus Professor of Medicine at IU SoM, Regenstrief Professor of Medical Informatics, National Academy of Medicine member (aka Institute of Medicine) and now Chief Health Informatics Officer of Cerner Corporation.
- Bruce M. Psaty, MD, PhD, Professor of General Internal Medicine and Epidemiology at the University of Washington School of Public Health, and Adjunct Professor of Health Services. (Bruce was a Medical Resident engaged in epidemiologic research project , not a medical informatics fellow.)
- Susanne Ragg MD, PhD, Associate Professor of Pediatric Medicine at IU SoM.
- David M. Smith, MD, Professor of Medicine Emeritus at IU SoM.
- William "Bill" Tierney, MD, Emeritus Sam Regenstrief Professor of Health Services Research and Medicine at IU SOM, Emeritus President of the Regenstrief Institute, Member of the National Academy of Medicine (aka IOM), 2011 Morris Collen Award Winner, and now the inaugural Chair of the Department of Population Health at the Dell Medical School at The University of Texas at Austin.
- Daniel J. Vreeman, PT, DPT, MSC, Associate Research Professor of Medicine at IU SoM, and Associate Director for Terminology Services at the Regenstrief Institute, where he directs the development of LOINC . Greg Wilson, MD, Emeritus Professor of Pediatrics at IU SoM, Emeritus State Health Commissioner of Indiana Department of Public Health, Director of Indiana State Department of Health, and Associate Chair of Community and Global Health.

neatest program ever set up anywhere on Earth. He set up a program where two residents at a time could get off their rotation, and in a year, they'd do a research project collectively, so there'd be 12 of them in a year. They published papers, based on their year of work. It was just really neat. And of those who participated, I think something like 80 percent of them went into research.

Others told Bill, "You're wasting your time. How can you do it with part-time guys?" But they met once a month or twice a month, all together, all year round. That was hard on the residents, because they had night call. It was just a neat, neat thing. There are some big names that came out of that. Bruce Psaty at University of Washington, who's a big epidemiologist in cardiology. He's the one who reported the severe danger of the regular nifedipine pill. He has a huge CV and is a very well-known guy. Bill was also the one who wrote the NLM training grant and got the NLM grant money for the NLM fellowship in 1997. I was barely able to stay afloat with my other work at that time.

Source: Personal collection of Phil Kroth.

Clem McDonald, April 2003, with Regenstrief Institute fellows Phil Kroth, Burke Mamlin, Paul Biondich, John Finnell, and Shaun Grannis.

JA ***For the regular fellowship program?***

CM For the formal NLM fellowship program, which started about 7 years ago. Then, in 1997, he took on a bunch of other responsibilities and said he couldn't do it anymore. We didn't want it to disappear, so he asked, "Would you do it?" I said I would. He didn't think I would really spend the time. But I did. I met with the NLM fellows every Friday morning, as a group, and intermittently, individually, for various projects and various parts. Some of them are in this photo with Octo Barnett. It has been a ball.

JA ***You took it over when?***

CM I think 1997. He basically said, "I didn't think you'd do that."

JA ***Well, I think that we've exhausted all of us, ourselves. We will continue this, because I think these other issues are really important. So let's put that on hold.***

DS ***Yeah, that'd be great.***

CM Thank you.

[Published April 7, 2017]

For additional Conversations with Medical Informatics Pioneers, please visit:

http://lhncbc.nlm.nih.gov/project/medical-informatics-pioneers

References

1. U.S. National Library of Medicine, AMIA. Clem McDonald 2004 ACMI Morris F Collen Award - YouTube. *YouTube* 2004. Available at: https://www.youtube.com/watch?v=fnqg6u8SeZo&feature=youtu.be. Accessed January 4, 2017.
2. Overhage JM. Presentation of the Morris F. Collen Award to Clement J. McDonald, MD. *J. Am. Med. Inform. Assoc.* 2005;12(2):241-4.
3. McDonald CJ. Use of a Computer to Detect and Respond to Clinical Events: Its Effect on Clinical Behavior. *Ann Intern Med* 1976;34(7):162-167.
4. McDonald CJ. Protocol-Based Computer Reminders, The Quality of Care and the Non-Perfectability of Man. *N Engl J Med* 1976;295(24):1351-1355.
5. McDonald CJ, Wiederhold G, Simborg DW, Hammond E, Jelovsek FR, Schneider K. A Discussion of the Draft Proposal for Data Exchange Standards for Clin Lab Results. In: *Annu Symp Comput Appl Med Care*.; 1984:406-413.
6. McDonald CJ, Hammond WE. Standard Formats for Electronic Transfer of Clinical Data. *Ann Intern Med* 1989;110(5):333-335.
7. McDonald CJ. Standards for the Electronic Transfer of Clinical Data: Progress, Promises, and the Conductor's Wand. In: *Ann Symp Comp Appl Med Care*.; 1990:9-14.
8. Health Level Seven International. HL7 Standards Product Brief - HL7 Messaging Standard Version 2.3.1. Available at: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=141. Accessed January 4, 2017.
9. Forrey AW, McDonald CJ, DeMoor G, Huff SM, Leavelle D, Leland D, Fiers T, Charles L, Griffin B, Stalling F, Tullis A, Hutchins K, Baenziger J. Logical observation identifier names and codes (LOINC) database: a public use set of codes and names for electronic reporting of clinical laboratory test results. *Clin Chem* 1996;42(1):81-90.
10. McDonald CJ, Overhage JM, Tierney WM, Dexter PR, Martin DK, Suico JG, Zafar A, Schadow G, Blevins L, Glazener T, Meeks-Johnson J, Lemmon L, Warvel J, Porterfield B, Cassidy P, Lindbergh D, Belsito A, Tucker M, Williams B, Wodniak C. The Regenstrief Medical Record System: a quarter century experience. *Int J Med Inf.* 1999;54(3):225-253.
11. McDonald CJ. The Clinical Automaton—An Ambulatory Care Record with Control Capabilities. In: *IEEE Conf Cyber Soc*. IEEE; 1973:27-31.
12. McDonald CJ, Bhargava B. Ambulatory Care Information Systems Written in BASIC-Plus. *DECUS Proc. Fall 1973* 1973.
13. McDonald CJ, Bhargava B, Jeris D. A Clinical Information System (CIS) for Ambulatory Care. In: *AFIPS National Computer Conference*. Anaheim, CA; 1975:749-756.
14. McDonald CJ, Hammond W, Wiederhold G, Jelovsek F, Simborg D, Schneider K. A discussion of the draft proposal for data exchange standards for clinical laboratory results. *Eighth Annu. Symp. Comput. Appl. Med. Care, Washington, DC* 1984;1984:406-413.
15. ASTM. Standard specifications for transferring clinical observations between independent computer systems. E-1238-88. 1988.
16. Huff SM, Rocha RA, McDonald CJ, De Moor GJ, Fiers T, Bidgood Jr. WD, Forrey AW, Francis WG, Tracy WR, Leavelle D, Stalling F, Griffin B, Maloney P, Leland D, Charles L, Hutchins K, Baenziger J. Development of the Logical Observation Identifier Names and Codes (LOINC) vocabulary. *J Am Med Inf. Assoc* 1998;5(3):276-292.
17. Vreeman DJ, McDonald CJ, Huff SM. LOINC® - A Universal Catalog of Individual Clinical Observations and Uniform Representation of Enumerated Collections. *Int. J. Funct. Inform. Personal. Med.* 2010;3(4):273-291. doi:10.1504/IJFIPM.2010.040211.
18. Vreeman DJ, Chiaravalloti MT, Hook J, McDonald CJ. Enabling international adoption of LOINC through translation. *J. Biomed. Inform.* 2012;45(4):667-73. doi:10.1016/j.jbi.2012.01.005.
19. McDonald CJ. Standards for medical identifiers, codes, and messages needed to create an efficient computer-stored medical record. American Medical Informatics Association. Andrade JD, ed. *J Am Med Inf. Assoc* 1994;1(1):118-126.
20. Schadow G, McDonald CJ, Suico JG, Fohring U, Tolxdorff T. Units of measure in clinical information systems. *J Am Med Inf. Assoc* 1999;6(2):151-162.
21. Schadow G, McDonald CJ. The Unified Code for Units of Measure (UCUM). Available at: http://unitsofmeasure.org/. Accessed January 29, 2015.
22. U.S. National Library of Medicine, The Regenstrief Institute. Common UCUM Units — LOINC. 2011. Available at: http://loinc.org/usage/units. Accessed January 29, 2015.
23. McDonald CJ, Schadow G, Suico J, Overhage JM. Data standards in health care. *Ann Emerg Med* 2001;38(3):303-311. doi:10.1067/mem.2001.117947.
24. Warner HR, Ash JS, Sittig DF. Founder of the HELP System and the Utah Medical Informatics Program: 2005 Interview of Homer R. Warner, Sr. Goodwin RM, Ash JS, Sittig DF,

eds. *Conversations with Med. Informatics Pioneers An oral Hist. Proj.* 2015. Available at: https://lhncbc.nlm.nih.gov/publication/pub9121.

25. Warner HR, Toronto AF, Veasy LG, Stephenson R. A mathematical approach to medical diagnosis: Application to congenital heart disease. *JAMA* 1961;177(3):177-83.

26. Warner HR, Toronto AF, Veasy LG. Experience with Baye's Theorem for Computer Diagnosis of Congenital Heart Disease. *Ann. N. Y. Acad. Sci.* 1964;115:558-67.

27. Peacock AC, Bunting SL, Brewer D, Cotlove E, Williams GZ. Data Processing in Clinical Chemistry. *Clin. Chem.* 1965;11(5):595-611.

28. Enroth-Cugell C, Mockros LF, Linsenmeier RA. Biomedical Engineering at Northwestern 1969-1999. 2001. Available at: www.bme.northwestern.edu/docs/bme_history2.pdf.

29. Lewis S. *Hospital: An Oral History of Cook County Hospital*. New York, NY: The New Press; 1995.

30. Safran C. Presentation of Morris F. Collen Award to professors Howard Bleich and Warner Slack. *J. Am. Med. Inform. Assoc.* 2002;9(4):406-8.

31. U.S. National Library of Medicine, AMIA. 2001 Morris F. Collen Award: Howard L. Bleich and Warner V. Slack - YouTube. *YouTube* 2001. Available at: https://www.youtube.com/watch?v=79_0L2iedKU. Accessed January 4, 2017.

32. Meridian International Center. Peace Corps medical partnerships. *Small Things Rememb. early years U.S.-Afghan relations.* Available at: http://www.meridian.org/insmallthingsremembered/peace-corps-medical-partnerships. Accessed February 18, 2016.

33. Syangboche Airport and the Everest Sherpa Resort. Available at: http://www.everestresort.com/syangboche.php. Accessed July 1, 2016.

34. Hotel Everest View. Available at: http://hoteleverestview.com/. Accessed July 1, 2016.

35. Masys DR, Ellison D, Stead WW. Presentation of the 2007 Morris F. Collen award to William W. Stead, MD, including comments from recipient. *J. Am. Med. Inform. Assoc.* 2008;15(3):302-6. doi:10.1197/jamia.M2739.

36. Stead WW. Presentation of the Morris F Collen Award to William Edward Hammond II, PhD. *J. Am. Med. Inform. Assoc.* 2004;11(3):221-4.

37. U.S. National Library of Medicine, AMIA. 2003 Morris F. Collen Award: W. Edward Hammond - YouTube. *YouTube* 2003. Available at: https://www.youtube.com/watch?v=hPMNGQewOj8. Accessed January 4, 2017.

38. Revelation BASIC programming language. Available at: http://www.fact-index.com/r/re/revelation_basic_programming_language.html. Accessed January 4, 2017.

39. VAX BASIC User Manual. 1990. Available at: ftp://bitsavers.informatik.uni-stuttgart.de/pdf/dec/vax/lang/basic/AA-HY15B-TE_VAX_BASIC_User_Manual_Feb90.pdf. Accessed January 4, 2017.

40. Fowler EM. Samuel Regenstrief, 78. *New York* 1988. Available at: http://www.nytimes.com/1988/01/20/obituaries/samuel-regenstrief-78-is-dead.html. Accessed August 12, 2015.

41. The Regenstrief Institute. *Sam Regenstrief: Legacy of the Dishwasher King.*; 1998.

42. Barnett GO, Ash JS, Sittig DF. From "Farm Boy" to Director of the Laboratory of Computer Science: 2004 Interview of G. Octo Barnett. Goodwin RM, Ash JS, Sittig DF, eds. *Conversations with Med. Informatics Pioneers An oral Hist. Proj.* 2015. Available at: https://lhncbc.nlm.nih.gov/publication/pub9124.

43. Greenes RA. Presentation of the Morris F. Collen Award to G. Octo Barnett, MD, by Robert A. Greenes, MD, PhD. *J. Am. Med. Inform. Assoc.* 1997;4(2):155-60.

44. Collen MF, Sittig DF. Engineering Computerized Multiphasic Health Screening: 2005 Interview of Morris F. Collen, MD. Goodwin RM, Ash JS, Sittig DF, eds. *Conversations with Med. Informatics Pioneers An oral Hist. Proj.* 2015. Available at: https://lhncbc.nlm.nih.gov/publication/pub8940.

45. McDonald CJ, Wilson GA, McCabe GP. Physician Response to Computer Reminders. *JAMA* 1980;244:1579-1581.

46. McDonald CJ, Hui S, Smith D, Tierney WM, Cohen S, Weinberger M, McCabe GP. Reminders to Physicians from an Introspective Computer Medical Record. A Two-year Randomized Trial. *Ann Intern Med* 1984;100:130-138.

47. Tierney WM, Hui S, McDonald CJ. Delayed Feedback of Phys Performance Vs Immediate Reminders to Perform Preventive Care. Effects on Phys Compliance. *Med Care* 1986;24(8):659-666.

48. Johnston ME, Langton KB, Haynes RB, Mathieu A. Effects of Computer-based Clinical Decision Support Systems on Clinician Performance and Patient Outcome: A Critical Appraisal of Research. *Ann. Intern. Med.* 1994;120(2):135. doi:10.7326/0003-4819-120-2-199401150-00007.

49. Langton KB, Johnston ME, Haynes RB, Mathieu A. A critical appraisal of the literature on the effects of computer-based clinical decision support systems on clinician performance and patient outcomes. *Proc. Annu. Symp. Comput. Appl. Med. Care* 1992:626-30.

50. Overhage JM, Tierney W, Abernathy G, McDonald CJ. Secrets of the Reminder Gurus: How to Change Physician Behavior with Information. In: *Towards an Electronic Patient Record.*; 1996:457-461.

51. McDonald CJ, Overhage JM, Mamlin BW, Dexter PD, Tierney WM. Physicians, information technology, and health care systems: a journey, not a destination. *J Am Med Inf. Assoc* 2004;11(2):121-124. doi:10.1197/jamia.M1488.

52. Tierney WM, McDonald CJ, Martin DK, Hui S, Rogers MP. Computerized Display of Past Test Results- Effect on Outpatient Testing. *Ann Intern Med* 1987;107:569-574.

53. Tierney WM, McDonald CJ, Hui S, Martin D. Computer Predictions of Abnormal Test Results - Effects on Outpatient Testing. *JAMA* 1988;259(8):1194-1198.

54. Tierney WM, Miller ME, McDonald CJ. The Effect on Test Ordering of Informing Phys of the Charges for Outpatient Diag Tests. *N Engl J Med* 1990;322(21):1499-1504.

55. McDonald CJ, Hui S, Tierney WM. Effects of Computer Reminders for Influenza Vaccinations on Morbidity During Influenza Epidemics. *MD Comput* 1992;9(5):304-312.

56. Tierney WM, Miller ME, Overhage JM, McDonald CJ. Physician inpatient order writing on microcomputer workstations. Effects on resource utilization. *JAMA* 1993;269(3):379-383.

57. Litzelman DK, Dittus RS, Miller ME, Tierney WM. Requiring physicians to respond to computerized reminders improves their compliance with preventive care protocols. *J. Gen. Intern. Med.* 1993;8(6):311-7.

58. Dexter PR, Wolinsky FD, Gramelspacher GP, Zhou XH, Eckert GJ, Waisburd M, Tierney WM. Effectiveness of computer-generated reminders for increasing discussions about advance directives and completion of advance directive forms. A randomized, controlled trial. *Ann. Intern. Med.* 1998;128(2):102-10.

59. Murray MD, Loos B, Tu W, Eckert GJ, Zhou X-H, Tierney WM. Effects of Computer-based Prescribing on Pharmacist Work Patterns. *J. Am. Med. Informatics Assoc.* 1998;5(6):546-553. doi:10.1136/jamia.1998.0050546.

60. Overhage JM, Perkins S, Tierney WM, McDonald CJ. Controlled trial of direct physician order entry: effects on physicians' time utilization in ambulatory primary care internal medicine practices. *J Am Med Inf. Assoc* 2001;8(4):361-371.

61. Murray MD, Harris LE, Overhage JM, Zhou X-H, Eckert GJ, Smith FE, Buchanan NN, Wolinsky FD, McDonald CJ, Tierney WM. Failure of computerized treatment suggestions to improve health outcomes of outpatients with uncomplicated hypertension: results of a randomized controlled trial. *Pharmacotherapy* 2004;24(3):324-37.

62. Dexter PR, Perkins SM, Maharry KS, Jones K, McDonald CJ. Inpatient computer-based standing orders vs physician reminders to increase influenza and pneumococcal vaccination rates: a randomized trial. *JAMA* 2004;292(19):2366-71. doi:10.1001/jama.292.19.2366.

63. McDonald CJ. The medical gopher--a microcomputer based physician work station. *Annu Symp Comput Appl Med Care* 1984:453-459.

64. McDonald CJ, Tierney WM. The Medical Gopher-A Microcomputer System to Help Find, Organize and Decide About Patient Data. *West J Med* 1986;145(Dec):823-829.

65. Tierney WM, Overhage JM, McDonald CJ, Wolinsky FD. Medical students' and housestaff's opinions of computerized order-writing. *Acad Med* 1994;69(5):386-389.

66. Overhage JM, Tierney WM, McDonald CJ. Computer reminders to implement preventive care guidelines for hospitalized patients. *Arch Intern Med* 1996;156(14):1551-1556.

67. Overhage JM, Tierney WM, Zhou XH, McDonald CJ. A randomized trial of "corollary orders" to prevent errors of omission. *J Am Med Inf. Assoc* 1997;4(5):364-375.

68. Dexter PR, Perkins S, Overhage JM, Maharry K, Kohler RB, McDonald CJ. A computerized reminder system to increase the use of preventive care for hospitalized patients. *N Engl J Med* 2001;345(13):965-970. doi:10.1056/NEJMsa010181.

69. Kroth PJ, Dexter PR, Overhage JM, Knipe C, Hui SL, Belsito A, McDonald CJ. A computerized decision support system improves the accuracy of temperature capture from nursing personnel at the bedside. *AMIA Annu Symp Proc* 2006:444-448.

70. McDonald CJ, Tierney WM, Overhage JM, Martin D, Wilson G. The Regenstrief Medical Record System 20 years experience in hospital outpatient clinic and neighborhood health centers. *MD Comput* 1992;9(4):206-217.

71. Wilson G, McDonald CJ, McCabe GP. The Effect of Immediate Access to Comput Med Record on Phys Test OrderingA Controlled Clin Trial. *Am J Public Heal.* 1982;72:698-702.

72. Kho AN, Dexter PR, Warvel JS, Belsito AW, Commiskey M, Wilson SJ, Hui SL, McDonald CJ. An effective computerized reminder for contact isolation of patients colonized or infected with resistant organisms. *Int. J. Med. Inform.* 2008;77(3):194-8. doi:10.1016/j.ijmedinf.2007.02.005.

73. McDonald CJ. Medical heuristics: the silent adjudicators of clinical practice. *Ann Intern Med* 1996;124(1 Pt 1):56-62.

74. Warner HR, Olmsted CM, Rutherford BD. HELP--a program for medical decision-making. *Comput. Biomed. Res.* 1972;5(1):65-74.

75. Warner HR. First the electrocardiogram--then what? A system for decision-making by computer. *Am. J. Cardiol.* 1978;41(1):115-8.

76. Ash JS, Sittig DF. *Conversations with Medical Informatics Pioneers: An Oral History Collection*. (Goodwin RM, Ash JS, Sittig DF, eds.). Bethesda: U.S. National Library of Medicine; 2015.

77. McDonald CJ. Music, MIDI and Medical Data Exchange Standards Laboratory Data Exchange Standard. *MD Comput* 1988;5(3):8-13.

78. McDonald CJ, Jernigan DB, Williams W, Stahlecker C. LOINC & HL7 for Clinical Observations, Public Health, and Claims Attachments. In: *AMIA Annu Symp.*; 1999.

79. McDonald CJ, Huff SM, Suico JG, Hill G, Leavelle D, Aller R, Forrey A, Mercer K, DeMoor G, Hook J, Williams W, Case J, Maloney P. LOINC, a universal standard for identifying laboratory observations: a 5-year update. *Clin. Chem.* 2003;49(4):624-33.

80. Vreeman DJ, McDonald CJ. Automated mapping of local radiology terms to LOINC. *AMIA Annu. Symp. Proc.* 2005:769-73.

81. Vreeman DJ, McDonald CJ, Huff SM. Representing Patient Assessments in LOINC®. *AMIA ... Annu. Symp. proceedings. AMIA Symp.* 2010;2010:832-6.

82. Abhyankar S, Lloyd-Puryear MA, Goodwin R, Copeland S, Eichwald J, Therrell BL, Zuckerman A, Downing G, McDonald CJ. Standardizing newborn screening results for health information exchange. *AMIA Annu. Symp. Proc.* 2010;2010:1-5.

83. Abhyankar S, Therrell BL, Eaton R, Cuthbert C, Ojodu J, Copeland S, Goodwin RM, McDonald CJ. Using LOINC and HL7 to standardize hemoglobinopathy screening result reporting. *APHL Newborn Screen. Genet. Test. Symp.* 2011.

84. Deckard J, McDonald CJ, Vreeman DJ. Supporting interoperability of genetic data with LOINC. *J. Am. Med. Inform. Assoc.* 2015. doi:10.1093/jamia/ocu012.

85. Abhyankar S, Goodwin RM, Sontag M, Yusuf C, Ojodu J, McDonald CJ. An update on the use of health information technology in newborn screening. *Semin. Perinatol.* 2015;39(3):188-193. doi:10.1053/j.semperi.2015.03.003.

86. Hripcsak G. Writing Arden Syntax Medical Logic Modules. *Comput. Biol. Med.* 1994;24(5):331-63.

87. McDonald CJ. *Action Oriented Decisions in Ambulatory Medicine*. Chicago, IL: Yearbook Medical Publishers; 1981. doi:9780815158097.

88. McDonald CJ, Bhargava B, Jeris D. A Clinical Information System (CIS) for Ambulatory Care. In: *AFIPS National Computer Conference*. Anaheim, CA; 1975:749-756.

89. McDonald CJ, Jeris D, Seeger J, Blevins L, McKee J. The Use of the Computer to Execute Simple Medical Decisions. In: *Society Computer Medicine*.Vol 8.4.; 1976:1-5.

90. McDonald CJ, Murray R, Jeris D, Bhargava B, Seeger J, Blevins L. A Computer based Record and Clinical Monitoring System for Ambulatory Care. *Am J Public Heal.* 1977;67:240-245.

91. McDonald CJ, Glazener T, Blevins L, Haas J, Lemmon L, Meeks-Johnson J. Data Base Management, Feedback Control and the Regenstrief Medical Record. *J Med Syst* 1983;7(2):111-125.

92. McDonald CJ, Blevins L, Glazener T, Lemmon L, Martin D, Valenza M. CARE A Real World Medical Knowledge Base. In: *Compcon 28th IEEE Computer Society Intl Conference*.; 1984:187-191.

93. McDonald CJ, Blevins L, Tierney WM, Martin DK. The Regenstrief medical records. *MD. Comput.* 1988;5(5):34-47.

94. McDonald CJ, Day Z, Martin D, Tierney WM, Blevins L, Mamlin B, Meeks-Johnson J, Porterfield B, Warvel JA, Warvel J. The Regenstrief Medical Record 1989- A Campus-wide System. In: Kingsland LC, ed. *13th Ann Symp Comput Applications in Med Care*. Washington, DC; 1989:933-936.

95. Golichowski AM, McDonald CJ, Tierney WM, Overhage JM, Brown H, Lemmon L, Blevins L, Meeks-Johnson J, Glazener T. Managing Perinatal Data with the Regenstrief Medical Record System. *J Ambul Care Manag.* 1992;15(4):40-53.

96. McDonald CJ, Tierney W, Overhage JM, Dexter P, Takesue BY, Abernathy G. The Three Legged Stool Regenstrief Institute for Health Care. In: *3rd Annual N. E. Davis CPR Recognition Symposium*.; 1997:101-147.

97. Overhage JM, Aisen A, Barnes M, Tucker M, McDonald CJ. Integration of radiographic images with an electronic medical record. In: *Proc AMIA Symp*. 2002/02/05.; 2001:513-517.

98. Mamlin BW, Overhage JM, Tierney W, Dexter P, McDonald CJ. Clinical Decision Support Within the Regenstrief Medical Record System. In: Berner ES, ed. *Clinical Decision Support Systems Theory and Practice*. New York: Springer; 2007:190-214.

99. McDonald CJ, Hui SL, Tierney WM. Diuretic-induced laboratory abnormalities that predict ventricular ectopy. *J. Chronic Dis.* 1986;39(2):127-35.

100. Tierney WM, Martin D, Hui S, McDonald CJ. Using Clinical Data to Predict Abnormal Serum Electrolytes Blood Cell Profiles. *J Gen Intern Med* 1989;4(5):375-383.

101. Murray MD, Brater DC, Tierney WM, Hui SL, McDonald CJ. Ibuprofen-associated renal impairment in a large general internal medicine practice. *Am. J. Med. Sci.* 1990;299(4):222-9.

102. Mahon BE, Rosenman MB, Kleiman MB. Maternal and infant use of erythromycin and other macrolide antibiotics as risk factors for infantile hypertrophic pyloric stenosis. *J. Pediatr.* 2001;139(3):380-4. doi:10.1067/mpd.2001.117577.

103. Kho AN, Hui S, Kesterson JG, McDonald CJ. Which observations from the complete blood cell count predict mortality for hospitalized patients? *J. Hosp. Med.* 2007;2(1):5-12. doi:10.1002/jhm.143.

104. McDonald CJ, Tierney WM. Research Uses of Computer-stored Practice Records in General Medicine. *J Gen Intern Med* 1986;1:S19-S24.

105. Tierney WM, McDonald CJ. Practice Databases and Their Uses in Clinical Research. *Stat Med* 1991;10:541-557.

106. Tierney WM, Miller ME, Hui S, McDonald CJ. Practice Randomization and Clinical Research The Indiana Experience. *Med Care* 1991;29(7):JS57-JS64.

107. Wall JK. Exchanges sprout around the country. *Indiana Bus. J.* 2010. Available at: http://www.ibj.com/articles/21324-exchanges-sprout-around-the-country. Accessed January 29, 2015.

108. Overhage JM, Tierney WM, McDonald CJ. Design and implementation of the Indianapolis Network for Patient Care and Research. *Bull Med Libr Assoc* 1995;83(1):48-56.

109. Sears CS, Prescott VM, McDonald CJ. The Indiana Network for Patient Care: A Case Study of a Successful Healthcare Data Sharing Agreement. *Am Bar Assoc Heal. eSource* 2005.

110. McDonald CJ, Overhage JM, Barnes M, Schadow G, Blevins L, Dexter PR, Mamlin B, Committee IM. The Indiana network for patient care: a working local health information infrastructure. An example of a working infrastructure collaboration that links data from five health systems and hundreds of millions of entries. *Heal. Aff* 2005;24(5):1214-1220. doi:10.1377/hlthaff.24.5.1214.

111. Tierney WM, Overhage JM, Murray MD, Harris LE, Zhou X-H, Eckert GJ, Smith FE, Nienaber N, McDonald CJ, Wolinsky FD. Effects of computerized guidelines for managing heart disease in primary care. *J. Gen. Intern. Med.* 2003;18(12):967-76.

112. Subramanian U, Fihn SD, Weinberger M, Plue L, Smith FE, Udris EM, McDonell MB, Eckert GJ, Temkit M, Zhou X-H, Chen L, Tierney WM. A controlled trial of including symptom data in computer-based care suggestions for managing patients with chronic heart failure. *Am. J. Med.* 2004;116(6):375-384. doi:10.1016/j.amjmed.2003.11.021.

113. McDonald CJ, Overhage JM. Guidelines you can follow and can trust. An ideal and an example. *JAMA* 1994;271(11):872-873.

114. Stiell IG, Greenberg GH, McKnight RD, Nair RC, McDowell I, Reardon M, Stewart JP, Maloney J. Decision rules for the use of radiography in acute ankle injuries. Refinement and prospective validation. *JAMA* 1993;269(9):1127-32.

115. Stiell I, Wells G, Laupacis A, Brison R, Verbeek R, Vandemheen K, Naylor CD. Multicentre trial to introduce the Ottawa ankle rules for use of radiography in acute ankle injuries. Multicentre Ankle Rule Study Group. *BMJ* 1995;311(7005):594-7.

116. McDonald CJ. The barriers to electronic medical record systems and how to overcome them. *J Am Med Inf. Assoc* 1997;4(3):213-221.

117. McDonald CJ, Overhage JM, Dexter P, Takesue B, Suico JG. What is done, what is needed and what is realistic to expect from medical informatics standards. *Int J Med Inf.* 1998;48(1-3):5-12.

118. Zafar A, Overhage JM, McDonald CJ. Continuous speech recognition for clinicians. *J Am Med Inf. Assoc* 1999;6(3):195-204.

119. U.S. National Library of Medicine. SNOMED Clinical Terms® (SNOMED CT®).

120. Brooks Jr. FP. *The Mythical Man-Month: Essays on Software Engineering.* 2nd ed. Addison-Wesley; 1995. doi:0201835959.

121. McDonald CJ. Nonassociation of Adrenocortisteroids [Letter to the Editor]. *N Engl J Med* 1976;294(23):1292.

122. McDonald CJ, Rogers MP. Household risk of AIDS [Letter]. *N Engl J Med* 1986:258.

123. McDonald CJ, Mazzuca S, McCabe GP. How Much of the Placebo Effect is Really Statistical Regression. *Stat Med* 1983;2:417-427.

124. Institute of Medicine. *To Err Is Human: Building A Safer Health System - Institute of Medicine*.; 1999.

125. Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century.* The National Academies Press; 2001.

126. McDonald CJ, Weiner M, Hui SL. Deaths due to medical errors are exaggerated in Institute of Medicine report. *JAMA* 2000;284(1):93-95.

127. McDonald CJ, Weiner M, Hui S, Hughes CM. How Many Deaths Are Due to Medical Errors? [Letter]. *JAMA J. Am. Med. Assoc.* 2000;284(17):2187. doi:10.1001/jama.284.17.2187.

128. McDonald CJ, Overhage JM, Dexter PR, Blevins L, Meeks-Johnson J, Suico JG, Tucker MC, Schadow G. Canopy computing: using the Web in clinical practice. *JAMA* 1998;280(15):1325-9.

129. American Medical Informatics Association (AMIA). Position paper on standards for medical identifiers, codes and messages needed to Create an Efficient Computer-Stored Medical Record. *AMIA Annu Symp Proc* 1993;1(1):1-7.

130. Grannis SJ, Overhage JM, McDonald CJ. Analysis of identifier performance using a deterministic linkage algorithm. *Proc. AMIA Symp.* 2002:305-9.