Appendix 1: Canadian Task Force on Preventive Health Care

[Science] knows nothing of policy or utility, of better or worse.
Torsten Veblen, 1906

The scientist [has] neither the moral competence nor the moral right
to use the lecture-room or the learned journal
to pronounce what ought to be done.
Max Weber, 1918

Science never tells a man how he should act;
it merely shows how a man must act
if he wants to attain definite ends.
Ludvig von Mises, 1963

The Issue Advocate seeks to compel a particular decision,
while an Honest Broker of Policy Alternatives seeks
to enable the freedom of choice by a decision-maker.
Roger A. Pielke, Jr., 2007

The first two of those here highly-relevant, orientational quotes above we drew from an indirect source, The Scientific Life: A Moral History of a Late Modern Vocation (2008) by Steven Shapin. He also cites three notable definitions of vocation right up-front, none of them consistent with the self-proclaimed mission of the CFPTHC (below).

As epidemiological research inherently is in the service of the practice of community medicine, and as this practice – epidemiological – is community-level preventive medicine, it is educational for a student of this research to gain familiarity with the Canadian Task Force on Preventive Health Care. Two sources of information about it are (refs. 1, 2):

References:
1. http://canadiantaskforce.ca

“The [CTFPHC], previously known as the Canadian Task Force on Periodic Health Examination was established in ... 1976 by the Conference of Deputy Ministers of Health of the ten Canadian provinces. ... The particular characteristic that distinguishes the Task Force methodology from traditional approaches in decision-making on prevention issues is that evidence takes precedence over consensus. ... In the 1980s the Task Force methodology was adopted ... by the United States Preventive Services Task Force ... [both of them] developing guidelines for clinical practice and public health policy. ... In 2005, the [CTFPHC] was disbanded. In 2010 [it] has been established with the support of [Public Health Agency of Canada] and a renewed commitment and vision to continue its 25-year tradition of excellence.” (Ref. 1; italics ours).

The CTFPHC is (ref. 2, p. 7) “an independent panel composed primarily of clinicians and methodologists that makes recommendations for clinical preventive actions ... but its work is also directly relevant to other health care professionals, developers of preventive programs, policy makers and Canadian citizens. ... The services must be provided in primary care settings or available by primary care referral.”

“The CTFPHC uses the same definition of primary care as the US Institute of Medicine” (ref. 2, p. 36):

Primary care is the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. This definition acknowledges the importance of the patient clinician relationship as facilitated and augmented by teams and integrated delivery systems.

The CTFPHC is “an independent body of fifteen primary care and prevention experts who recognize and support the need for evidence informed preventive activities in primary care in Canada” (ref. 1). This body of experts is now chaired by a physician who is “a nephrologist, clinician-scientist and Associate Professor [in a Department of Medicine]” (ref. 1).

Having just been re-established, “The Task Force met in early 2010 to establish topic priorities and have begun the guideline development process. Topics being worked on in 2011 are:

- Screening for breast cancer
- Screening for hypertension
- Screening for depression
- Screening for diabetes
- Screening for cervical cancer
- Screening for obesity
- Screening for child obesity”

(ref. 1).
The CTFPHC classifies its recommendations as either “strong” or “weak.” In addition to “the quality of supporting evidence,” this classification is “influenced by

– the balance between desirable and undesirable effects;
– the variability or uncertainty in values and preferences of citizens; and
– whether or not the intervention represents a wise use of resources”

(ref. 1). A strong recommendation, either for or against an “intervention,” is one in the context of which the Task Force is “confident” that its desirable effects “outweigh” the undesirable ones or vice versa. Weak recommendation corresponds to this outweighing being only probable in the judgement of the Task Force. (Ref. 1.)

It thus remains unclear whether individuals’ values and society’s interest in cost-effectiveness actually bear on the recommendations. The example in Appendix 2 strongly suggests that they don’t.

So, the CTFPHC, continuing its “tradition of excellence,” still seems to be about “periodic health examinations” rather than “preventive health care,” though with the meaning of those examinations narrowed down to “screening.” And as will be evident from Appendix 2 below, the meaning of screening, too, is narrower than it might be expected to be: rather than all of that which is involved in the pursuit of latent-stage diagnosis (rule-in), it is narrowed down to the initial test in this pursuit (in the diagnostic algorithm) – even though the recommendations are directed to clinicians rather than community doctors. And most remarkably, that diagnostic test is taken to represent “intervention” and thus to have “desirable and undesirable effects” instead of being, merely, a source of information.

Regarding such a test – for example, mammography on a woman with no overt indication of having breast cancer, or weighing (?) a child with no overt indication of being obese (!) – the CTFPHC approaches decision-making about its use with a “methodology” in which “evidence takes precedence over consensus” and evidence presents itself with a given level of “quality” but not quantity. The essence of this methodology, in its bypassing of consensus, remains a mystery, however. It is illustrated in Appendix 2 below.
Appendix 2: CTFPHC on Screening for Breast Cancer

Drawing further from reference 1 in Appendix 1 above, there is this piece of news:

November 21, 2011 – The Canadian Task Force for Preventive Health Care has released an updated guideline for breast cancer screening in average risk women aged 40–74 . . . The new guideline, which weighs the potential harms of false positives and unnecessary biopsies against the potential benefits . . . updates prior guidelines by the Task Force from 1991 and 2001. (Italics ours; cf. App. 1 above.)

And there is also the guideline itself, separately for ages 40–49, 50–69, and 70–74, specifically in respect to mammography (as distinct from MRI and clinical breast examination). For this “intervention” the full specification is “mammography (film or digital) every 2 to 3 years.” Everything about the guideline is contained on a single page.

For those three ranges of age the respective Recommendations are: “not routinely screening,” “routinely screening,” and “routinely screening.” Each of these is characterized as “weak,” the first two on the ground of “moderate quality evidence,” the third based on “low quality evidence.” (For the meaning of “weak,” see App. 1 above.)

The Basis of Recommendation is specified, separately, for each of those three ranges of age. As an example, all that is said in reference to the age range 70–74 is this:

Women who do not place a high value on a small reduction in breast cancer mortality and are concerned about false positive results of mammography and overdiagnosis may decline screening. About 480 women aged 70–74 die of breast cancer in Canada each year.

Associated with that Recommendation and that Basis of it is this declaration:

To save one life from breast cancer over about 11 years in this age group [70–74],

– about 450 women would need to be screened every 2–3 years
– 11 women would have an unnecessary breast biopsy
– about 96 women will have a false positive mammogram leading to unnecessary anxiety and follow-up testing.
Besides, as for this range of age, “For every 1,000 women screened for about 11 years, about 5 women will unnecessarily undergo surgery for breast cancer” (italics ours).

To us it is very unclear what it is that thus is being said – and really meant – in respect to Canadian (sic; App. 1) women 70–74 years of age (who are “without personal or family history of breast cancer, without known BRCA 1 or 2 mutation, or prior chest wall radiation”). How can the option to “decline screening” be a “basis for recommendation” for screening? How can the annual number (sic) of breast-cancer deaths within this lustrum of age be a basis for recommendation about screening within this same, narrow range of age? or is it that at issue actually is initiation of screening in the early 1970s of age? And when said is that “To save one life from breast cancer over about 11 years in this age group [of 5 years], about 450 women would need to be screened every 2 to 3 years,” is this about periodic screening in the early 1970s or “over about 11 years” starting in the early 1970s? And is that statement about one averted death “over about 11 years” a statement about the duration of screening or about the time horizon for the averted death or both?

That statement about “every 1,000 women screened for about 11 years” presumably is about women in whom the screening is initiated in the early 1970s of age. Thus it presumably is about screening that could be continued up to age 86 or so. But: “No data from our review addresses the benefits of screening in women . . . older than 74,” implying that at issue actually is screening in the early 1970s only, for up to 5 years, and not “for about 11 years” starting at that age.

While the obfuscation in this guideline/recommendation statement is severe to the point of suggesting, to us, that it is intentional, science writers for newspapers evidently captured a simple message:

Five days after the publication of these guidelines/recommendations, a national newspaper of Canada (The Globe and Mail) announced, in a very prominent headline, that “Provinces re-evaluate breast screening.” The subheading read: “Health-care providers are taking a fresh look at their rules and the costs of administering them.” The article proper, by Renata D’Alesio, was about how those guidelines from the CPTFHC “have sparked a fiery national debate over which women should receive x-rays and how often.”

In that same issue of that paper, another eminent headline read, “Cures for cancer at any cost”; and the associated subheading was, “The benefits of breast and prostate screening have been proved exaggerated, but we are no less invested in them.” The author, Margaret Wente, ascribed that exaggeration idea to a statement, in 2009, by the chief medical officer of the American Cancer Society. Wente said that “The backlash [to the exaggeration idea] was ferocious. . . . The whole drama was repeated in Canada this week, . . . . The value of mammography screening, especially for younger women, has been decisively disproven. Many experts say it is of no value. Period.”

One week after these articles, a headline in the same newspaper read, “When emotion prevails over cold, hard science.” The subheading was, “Exceptionalism helps explain why mass breast cancer screening persists despite evidence it does
more harm than good.” The author, John Allemang, like his two predecessors (above), wrote as though he fully understood what the Task Force was saying. So he presented a very clear chart with the opening predicate: “If 2,100 women, 40–49, at average risk of breast cancer were screened every 2 years for 11 years.” In it he presented the consequent numbers of cases of harm, while only “1 woman would escape a breast-cancer death,” all of this pictorially illustrated.

The harms obviously would be incurred in the course of those 11 years, but what about the deaths that would be averted? By any reasonable presumption, the bulk of them would have occurred after that 11-year period of screening. Allemang did not indicate his understanding of what the Task Force meant in this regard, notably whether its time horizon for deaths was limited to those 11 years of screening; nor did he comment on his understanding of the relevance of the statistic that “About 470 women aged 40–49 die of breast cancer in Canada each year,” being that 11-year screening initiated at age 49 presumably bears on deaths in the 1970s, even. He wrote about what he saw as the implications of “cold, hard science” when the Task Force itself based its recommendations on “moderate quality evidence” and “low quality evidence” (cf. above).

As we, different from science writers for popular press, have difficulties in understanding what the Task Force is saying about screening for breast cancer, and as “The particular characteristic that distinguishes the Task Force methodology from traditional approaches in decision making on prevention issues is that evidence takes precedence over consensus” (App. 1 above), we took a look at the evidence that was used. This the Task Force specifies in the Canadian Medical Association Journal 2011; 183: 1991-2001.

We found that two of the seven trials used as the sources of evidence enrolled women in the 70–74 range of age. In these, the total number of women of this age assigned to the screening arm of the trials the CTFPHC reported to be 10,339, but based on the trial reports themselves we found it to be 10,339 + 296 = 10,635. The rest of the numbers are to the effect that the CTFPHC focused on the larger one of those experiences.

In this trial’s report the duration of screening on women aged 70–74 at its initiation is not given in the original report; but according to the PDQ website of the NCI (of the U.S.), its duration was 3 years, not “about 11 years.” The typical duration of follow-up (from entry into the trial) was 13 years overall but unspecified for those entering in the early 1970s of age.

The rates of death from breast cancer in the two subcohorts (N₁ = 10,339, N₀ = 7,307) evidently were derived, simply, as 49/10,339 and 50/7,307, their difference being 2.10/1,000, not 2.22/1,000. The “number needed to screen,” as defined (App. 1), thus was 1,000/2.10 = 480, not 450, at issue being screening for three (rather than about 11) years and death from breast cancer within 13 years (rather than ever). This 480 is but the statistical ‘point estimate’ from evidence so imprecise – as a matter of quantity rather than “quality” of the evidence – that the null P-value (one-sided) for the rate difference (and rate ratio) is as large as 0.04,
and derived from a study in which the “Risk of bias,” according to the CTFPHC, was “serious” – even with no regard for the incompleteness of the adherence to the regimens in the trial’s two arms.

The Task Force drew the evidence for the three ranges of age solely from seven randomized trials, evidently believing that these indeed represent the useful segment of the research, of the entirety of it. At the core of this belief is the idea – highly aberrant – that the initial test in screening is an intervention, together with the associated idea – common – that an intervention’s intended effect is to be studied by means of a randomized trial.

Such is the CTFPHC’s reverence of randomization in the continuation of its “tradition of excellence” that it seemingly takes no notice of the quality-relevant particulars of this, while others see a sequence of embarrassments in this regard.

In his cancer-focused *The Emperor of All Maladies* (2010), Siddhartha Mukherjee relates some of the sad stories. In the Health Insurance Plan trial in New York, the entries into the study cohorts, randomly separated as to intention-to-screen, were initially without any determination/confirmation of the asymptomatic status, the women in the control arm of the trial not even knowing of their involvement in the trial; and later, women who were symptomatic on entry were removed from the index cohort, but they could not be removed from the reference cohort (p. 297). “Edinburgh was a disaster. . . . [Various irregularities by both the doctors and the patients] confounded any meaningful interpretation of the study as a whole” (p. 298). And the nature of the randomization “completely undid the Canadian trial” (p. 298–9).

So here we have gained some insight into the Task Force working with its “renewed commitment and vision to continue its 25-year tradition of excellence” in which a distinguishing characteristic is that “evidence takes precedence over consensus” (App. 1). We see that this group makes authoritarian declarations of the form of knowledge (present or future tense) but with content that in principle is formed by mere results of studies, even very “low quality evidence” in this limited meaning of ‘evidence’; and what is much more, those declarations can be grossly counterfactual about the studies’ actual results. It is with this pseudo-knowledge as the principal input that the CTFPHC engages in its main mission: the faux pas (App. 1) of formulating authoritarian guidelines/recommendations for the practice of healthcare – clinical care.

Evidence per se, especially when misinterpreted (sect. 13.3) and seriously misrepresented, should not take precedence over consensus-seeking deliberations among genuine experts on a given topic of the knowledge-base of preventive healthcare (sect. 13.5) – of what is correctly understood to be preventive healthcare (see below).

Given what the CTFPHC says about its work in a general way (App. 1) and what it now says about screening for breast cancer specifically (above), and given also what science writers say about those new recommendations/guidelines (above), some additional critical comments are in order – for the student to “weigh and consider” (F. Bacon, sect. 1.4):
1. The CTFPHC classifies screening for a cancer (i.a.) as a matter of preventive medicine, invoking the concept of “secondary prevention” and saying that this is (by its own definition; ref. 2 in App. 1, p. 7) “directed to asymptomatic individuals with risk factors for a condition or preclinical disease (but not clinically evident disease).” But: our dictionary of medicine (Dorland’s, 28th edn.) defines preventive as “serving to prevent the occurrence of,” and preventive medicine, accordingly, as “that branch of study and practice which aims at the prevention of disease and promotion of health.” Secondary it defines as “second or inferior in order of time, place, or importance; derived from or consequent to a primary event or thing.”

2. The CTFPHC treats diagnostic testing, such as mammography, as an intervention. But: according to our medical dictionary (above), intervention is: “1. the act or fact of interfering so as to modify. 2. specifically, any measure whose purpose is to improve health or alter the course of a disease.” Mammography is but a type of initial testing in the pursuit of early, latent-stage detection of – rule-in of diagnosis about – breast cancer. Instead of an effect (in terms of improvement in the course of the cancer), its yield is information (about the latent presence of breast cancer). The associated intervention – potential only – is the cancer’s early treatment (in lieu of its alternative, late treatment upon the cancer already being overt, clinically manifest, symptomatic).

3. As the CTFPHC takes the purpose of mammography on asymptomatic women to be well exemplified by the concern “To save one life from breast cancer over about 11 years” and declares how many women “need to be screened every 2 to 3 years” to accomplish this, it leaves altogether unspecified the protocol/algorithm of the diagnostics-cum-treatment in each of those rounds of mammography; and the rest of the meaning also is obscure, to say the least (cf. above).

4. The meaning of this is not much clarified by the Procedure Manual of the CTFPHC (ref. 2 in App. 1). Said there (p. 36) is this:

   Evidence tables are also prepared, reporting information related to the key questions, the grade of evidence and the results. The Number Needed to Screen (NNS) is also calculated and added to the evidence table. NNS is calculated using the relative risk method: first a weighted relative risk (RR) must be calculated and then the number of lives saved per million \((1 – RR) \times \text{control group event rate per million}\) is calculated. Finally, the number needed to screen \((1,000,000/\text{lives saved per million})\) is calculated. … All calculations and presentation of data in the evidence set are rounded to four \([sic]\) decimal places.

5. While we had great difficulty understanding what the CTFPHC is now saying about screening for breast cancer and actually found the purportedly evidence-based statements to be seriously misleading about the evidence, and while the primary-care doctors receiving its Recommendations on screening for breast cancer likely are equally uncertain about what is meant, women do understand what a given round of screening for breast cancer is about: detecting and treating, at this time, a latent case of breast cancer, should a detectable case be present at this time – this with a view to the thus-enhanced prospects of cure
of the cancer. The word “cure” is in the title of Ms Wente’s column prompted by the recent CTFPHC report (cf. above) while no reference to this concern is made in that report.

6. The following should be agreeable by anyone seriously concerned with the intended consequences of mammographic screening for breast cancer:

   – There is to be a definition, for a given round of the screening, of the diagnostic algorithm in all relevant respects (all the way to the rule-in diagnosis following biopsy); and this is to be supplemented with definition of the treatment algorithm following the cancer’s rule-in diagnosis.

   – In reference to these regimens, the doctor’s, rational concern is to know, specifically for the woman at issue, at the time: (a) the probability that a single round of application of the defined diagnostic algorithm would result in rule-in diagnosis of the cancer’s presence; (b) the probability that the possibly detected cancer actually would be a life-threatening one; (c) the probability that the (possibly detected) cancer, if indeed life-threatening, would be curable by the defined early treatment while being incurable by any available late treatment; and (d) the time to the death that thus might be averted (ideally the probability distribution of this time, conditional on otherwise surviving).

These concerns are in sharp contrast to the CTFPHC’s “key question”: “Does screening with mammography . . . decrease mortality from breast cancer . . . ?”

7. As for the unintended, harmful consequences of such a defined single round of diagnostics and potential early treatment, the concern is to know, again for the woman at issue, at the time, the probabilities of: (a) positive result (as defined by the algorithm) of the initial mammography (nothing “false” about this so long as a correct algorithm is correctly followed); (b) biopsy resulting from the work-up following positive mammography (nothing “unnecessary” about this so long as, again, . . .); and (c) being treated for a cancer that actually is not life-threatening (cf. part ‘b’ above, the treatment in these cases, too, being necessary per the calculated risks accounted for in the protocol).

8. Even if all of this (nos. 6 and 7 above) be known from clinical (sic) research, unknown from research would remain the valuations that the particular woman at issue, at the time, associates with the probability of getting an already extant, latent case of otherwise fatal cancer cured by early treatment and with the probabilities of harms from the processes involved. All that the woman’s realistic doctor can possibly hope to provide is that scientific knowledge input to the decision. The woman herself brings the valuations and, then, integrates these two sets of inputs – informally – into a decision about (the round of) the screening at the time.

9. If the CTFPHC would understand the nature of the requisite knowledge-base for rational decisions about mammographic screening for breast cancer, it would realize that the relevant research remains essentially non-existent. While it should understand its proper research mission to be the formulation of the requisite
knowledge – experts’ consensus – alone (à la IARC; sect. 13.5), in the prevailing absence of the requisite knowledge it has a particularly compelling imperative to refrain from putting forward purportedly research-based recommendations for practice. And even if the scientific knowledge be there, it should understand that “[Science] knows nothing of policy or utility, of better or worse” (App. 1).

10. The CTFPHC, after having studied this Appendix, should also study Appendix 3 below and then reconsider its “renewed commitment and vision to continue its 25-year tradition of excellence” (App. 1).

11. The Public Health Agency of Canada (of which the CTFPHC is part; App. 1) should be clear on whether it still – in this era of national health insurance – upholds its ‘social contract’ in respect to medicine, continuing to respect the profession’s autonomy and limiting its public policies about, for example, screening for an illness to matters of cost reimbursement and its consequent concern for cost containment consistent with medically good-quality care (sect. 14.5).
Appendix 3: Needed Task Forces on Preventive Healthcare

Healthcare aimed at prevention of illness should be maximally scientific – not in the meaning of science telling doctors what to do (App. 1) but as a matter of having a rational theoretical framework together with knowledge-base from science. Preventive healthcare, when scientific, is directed to removal of known causes of illness (constitutional, environmental, and/or behavioral) or else to known ways to protect against their adverse effects on health. Scientific healthcare is knowledge-based – rather than ‘evidence-based’ – healthcare, with the understanding that the relevant knowledge is but part of the relevant inputs into decisions about preventive action.

While prevention-oriented health research abounds, it tends not to naturally translate into advancement of prevention-relevant knowledge (largely, we suggest, because of the prevailing nature of the scientific journalism surrounding medicine; sect. 13.6). There thus is a need for ‘task forces’ with the missions to seek to formulate the scientific knowledge for the multifarious sectors of preventive healthcare.

Paradigmatic to these task forces can be taken to be the International Agency for Cancer Research within the WHO. Even when focusing on a given substance as a possible carcinogen, it makes elaborate ad-hoc arrangements in forming topic-specific expert committees; and these, then, work very seriously in the pursuit of consensus opinions (expressly refraining from making policy recommendations for practice; sect. 13.5). Paradigmatic is not only the ad-hoc formulation of narrowly focused expert panels, this by an agency that itself is no slouch in these matters. Of major note also is the fact that the IARC does not form Canadian and U.S. panels, or Scandinavian and Russian ones. It understands that scientific issues are not country-specific but universal. It is, after all, an agency of the WHO. (All members of the CTFPHC are Canadian.)

So, in the framework of the WHO – or some other global organization concerned with preventive healthcare – there should be a number – large number – of task forces in the meaning of differentiated standing committees for preventive
healthcare. These task forces would not formulate their own consensus opinions on various topics; they would arrange suitable *ad-hoc panels* of even more differentiated, ultimate experts to do this.

One rather obvious example of these task forces would be that focused on radiation effects on health. It would arrange one expert committee to address the health implications of the use of mobile phones; another one focusing on the safety of the body scannings taking place at airports; and a third one on the health hazards attendant to medical imagings (incl. in screenings for cancers); etc.

The very multifarious topic of nutrition as a determinant of health would obviously require expertise very different from that having to do with radiation as a health hazard. In this centrally important area, at least two separate task forces would be needed, as the issues are so different between macro- and micronutrients.

In the formation of these, and other, task forces, one overarching principle is the one already insinuated by these examples: they should be differentiated according to the respective determinants they focus on, with no restriction on the health outcomes of concern. There thus should not be a task force for preventive cardiology, another for preventive oncology, etc. And there should not be separate task forces according to the recipients of the knowledge – general practitioners and community-level educators, for example.

À la IARC, the product from each expert panel should indeed be knowledge, not guidelines/recommendations. For, “Science never tells a man how he should act; …” (App. 1).

Related to all this, we’d like to propose, for good measure, one task force of a very different kind. The various expert panels focusing on their respective areas of prevention-relevant research would have a shared problem: they would need to pursue consensus essentially through their intra-panel discourse alone, given the paucity of *public discourse* on the evidence per se for one, and on inference from evidence for another (sect. 13.6). So, a useful purpose would be served by an undifferentiated, single Task Force on Prevention-oriented Science, making recommendations on how to improve the journalism environment of this enormously important segment of health science (cf. sect. 13.6).
Appendix 4: On Introductory Teaching of Scholars

K.S. Miettinen

An adequate introduction into a scholarly field might prepare the student for further studies, and perhaps for initial steps in practice; but an excellent introduction is more ambitious: it establishes the foundations needed for a career, perhaps half a century in duration, and it specifically plants, at the beginning of that career, those seeds which may, with suitable experience and reflection, mature into wisdom by the time of retirement. A sign of an excellent introductory text is that the student repeatedly returns to it, cherishes it, and continues to deepen his understanding of it throughout his career. As D’Alembert put it, “To completely understand the elements [of a science] requires more than simply knowing what they contain. One must also know their use, applications and consequences. . . . The distinctive trait of a good book about elements is leaving much to think about.”

In reviewing numerous cherished introductions on my technical bookshelf, a number of common characteristics stand out: the best introductions motivate the field, clarify concepts, establish methodology (perhaps abstracted from progression of method), identify points of divergence from and convergence with related fields, warn the student about logical and conceptual problems, and recommend approaches for prudently navigating those problems.

An example of excellent introductory texts is Linus Pauling’s “General Chemistry,” a text which has stood the test of time (since 1947) and changed how chemistry is taught, specifically in introductory courses. The text motivates chemistry by depicting the universe as being composed of matter and radiant energy; weaves an exposition of scientific methodology into the sequence of chapters in an incremental fashion; explains difficult concepts such as temperature with precision; and identifies points of divergence from and convergence with physics.

The present introduction into epidemiological research has these same qualities, as it moves from grappling with the essence of the field to the knowledge that has been achieved; clarifies important concepts such as the study base; and identifies points of convergence with and divergence from related fields such as statistics and sociology.
Points of divergence and convergence are often unknown to those who learn their field after it has reached steady state. For instance, a student searches in vain through modern introductions into logic for the reason why logic was reformulated in early twentieth century, or where modern logic diverges from classical logic. But fortunately, Alfred Tarski’s “Introduction to Logic and to the Methodology of Deductive Sciences” is still available. Tarski explains the revolution in logic in terms of establishing the foundations of mathematics (and deductive science more generally), and throughout the text he points out the corresponding simplifications (e.g., neglect of the logic of properties – a matter of meanings – as distinct from the logic of classes, properties being unnecessary for establishing foundations of mathematics). Tarski is a case in point of what W. Edwards Deming repetitively emphasized, that “teaching of beginners should be done by a master, not by a hack,” because so much of excellent introductory teaching consists of establishing nuanced understanding of fundamentals. An implication of masters teaching introductory courses is that these courses should generally have the highest students-to-teacher ratios, as beginners are the most common kind of student and masters the least common kind of teacher.

Tarski’s inside knowledge also includes recognition of something that Deming never pointed out, namely that among masters we should prefer those of that generation which participated in the most recent revolution in the field.

This introduction into epidemiological research presents the insights of a seminal participant in the most recent revolution in the field, the theory innovations of the 1970s. In this transition to developing introductory material the senior author follows in the footsteps of scholars such as Andrei Kolmogorov, who famously toward the end of his career chose to focus on publishing introductory texts, developing a new state program of education in mathematics, and teaching introductory courses to young elite students in the belief that cultivating mastery of fundamentals in the next generation of mathematicians was the most valuable contribution he could make.

All fields of scholarly study have logical and conceptual problems; only the most dogmatic (and least enlightened) teachers would present their field as being problem-free. For instance, among the conceptual problems in mathematics are the semantic problem of what particular numbers (such as “3”) mean, and the ontological problem of what infinity is. The solution of this in modern mathematics, via deployment of the abstract method, is to banish meanings of numbers as leading to too many fallacies; numbers are defined by the rules they follow without otherwise having any specific meaning. A good introduction (such as that of Timothy Gowers) tells the student that “for every number A apart from 0 there is a number C such that AC = 1” is a rule (the rule of multiplicative inverses), and that this is a rule for which zero is not an exception; it has no exceptions. Since the rules of arithmetic have no exceptions (else following the rules wouldn’t sufficiently define numbers) and infinity does not conform to the rules of arithmetic, infinity is not a number. Such are among the first conceptual problems that a student of mathematics should be introduced to; there are many others.
Logical problems in a science generally are of two kinds: problems within the field, and problems about the field. In mathematics, for instance, a good introduction would familiarize the student with Goldbach’s conjecture (a simple unproven apparent truth) and Wiles’ proof of Fermat’s last theorem (how can we know it is a proof?), as well as Skolem’s paradox (do we understand what a real number is?). Such problems do not need to be solved for the student to have a successful career in a field, but understanding their difficulty is effective inoculation against professional hubris.

Poor introductions, by contrast, misrepresent the field at issue through dangerous simplifications that may make delivering the content to the student easier, but at the risk of misleading the student as to truth. For instance, in one introduction into statistics I read that “the objective of statistics is to make an inference about a population based on information contained in a sample and to provide an associated measure of goodness for the inference.” This is, of course, a simplification that allows development of a mathematical body of statistical theory, but as a statement of objectives it is false in general, though perhaps true in special cases (such as opinion polling).

A better introduction into statistics would warn the student that this simplification, which undergirds the theory, is generally false, and that the general objective is to make inferences based on samples that can be validly applied beyond the population of which the sample is representative. For instance, the objective of the Framingham Heart Study surely was not limited to learning about the 1948 population of the town of Framingham. Going as far as is reasonable to validate inference from past data to future experience (a special form of the problem of inference to unsampled populations) without dogmatically reifying a metaphysical “state of nature” is the topic of Walter Shewhart’s parvum opus “Statistical Method from the Viewpoint of Quality Control,” a cherished introduction that I routinely reread. (Shewhart also addresses the more ambitious question of what evidence for the existence of a state of nature would look like; and as both Shewhart and his most prominent apostle Deming point out, all rigorous attempts to develop evidence indicating the existence of a state of nature have failed.)

Whereas all scholarly fields have logical problems, a good introduction explains those problems while demonstrating valid ways to navigate them. For example, Athanasios Papoulis’ classic introduction into “Probability, Random Variables, and Stochastic Processes” opens with a chapter on the logical difficulties with the very concept of probability (independence of the axioms and the various definitions), which leads to demonstration of how comparing the quantum mechanical theories of Maxwell/Boltzmann, Bose/Einstein, and Fermi/Dirac requires using three definitions of probability in a three-stage process. The classical (a priori) definition is used to develop quantum mechanical models, the axiomatic definition is implicit in the theory of probability with which the models are manipulated, and the relative frequency definition is used in empirical testing of the model predictions. The logical problem of developing the theory of probability is exposed to the student
rather than concealed, and prudent handling of the resulting difficulties is then demonstrated.

The present introduction to epidemiological research gives the student similar exposure to logical difficulties with what now are held as standard epidemiological methods (such as cohort and case-control studies), and presents their needed corrections.

Should any child of mine choose a career in epidemiological or related research I would look forward to their being taught from this text, by one of the authors or some other master, with the hope that the youngster would be a fertile receptor and career-long cultivator of the wisdom sown here.
Appendix 5: Quality Assurance for Modern Public-health Practice

K.S. Miettinen

I welcome the request (see Acknowledgements) to bring the perspective of industrial quality control at large to bear on what in this text is suggested for the industry of hospital-based healthcare (sect. 14.5). While agreeing with the suggestions in this text, I add some philosophically relevant background to motivate and augment the call to action.

The statistical and epistemological methods of W. Edwards Deming (originally of Walter Shewhart, Deming’s teacher) are central to modern industrial quality control, service industries included. The first two of his famous 14 points for management are: “Create constancy of purpose toward improvement” and “Adopt the new philosophy.”

Deming explained in his writings that while various stakeholders in an enterprise may have different interests – a labor representative may be concerned with employee morale and job security, investors and taxpayers with costs, consumer advocates with customer satisfaction, etc. – all of these concerns are interrelated, and regardless of which one is valued, the appropriate plan of action focuses, solely and constantly, on improvement of quality.

Thus, the pursuit of quality is an indirect means of pursuing myriad other things, which may or may not be publicly stated objectives. This is reflected in the observation in the present text that good healthcare is not only medically good but also economically good, that improving the medical quality of care is a way to indirectly pursue also other societal objectives related to healthcare.

In nominally pursuing improved quality, as Deming explained, we should really pursue greater uniformity of the goods produced or of the services provided. This point is rooted, first, in his insight that the causes of poor quality are also causes of variation in quality, so that effective pursuit of better quality and effective pursuit of more uniform quality are identical. And besides, he pointed out that while a rigorous epistemological basis for defining the limit to how far we can go exists for uniformity, it often does not exist for excellence. Thus, quality improvement should be pursued indirectly in terms of reduction in variation.
Finally, in nominally pursuing greater uniformity (lesser variation) of quality we should really pursue greater randomness of variation in quality. This point is rooted in his insight that a system whose variation of quality satisfies rigorous tests for randomness is unimprovable, no matter how broad the variation in quality happens to be; such a system can be replaced or redesigned, but its operation as designed is as good as can be achieved. On the other hand, a system whose variation of quality exhibits signs of nonrandomness can be improved by locating and removing the causes of nonrandom variation, no matter how narrow the range of variation already is. Greater uniformity too must be pursued indirectly, by eliminating nonrandomness rather than by directly addressing the variation.

Thus, industrial quality improvement à la Deming consists of two activities: continuous effort to identify assignable causes of variation in systems whose results show statistical evidence of nonrandomness, and regular redesign or replacement of systems apparently operating with only random variation. A notable implication of this is that while there may be acceptable levels of absolute quality and/or of variation of quality for some purposes, there is no acceptable level of either of these for the purposes of quality control. This is because, as I noted above, industrial quality control is an indirect means to achieving numerous other objectives (e.g., cost reduction), rather than just quality per se.

This insight of Deming’s is the basis of his exhortation to eliminate management by objective: there is no rational basis for setting a standard for what is acceptable. What is needed is constant pursuit of improvement, whatever be the level of performance already achieved.

Thus, in the quality improvement plan for Montfort Hospital cited in the text, the problem with the plan to ensure 65% compliance with handwashing protocols is not the absurdly low level of the goal; it is the very idea that an acceptable level can be rationally assigned. The plan should be to identify and eliminate assignable causes of variation in handwashing practices; and when that has been driven to the extreme of apparently no remaining assignable causes, then the follow-on plan should be to rethink and redesign workflows so that further improvements in the rate of handwashing can be made. Redesign of a system that is not yet in control is contraindicated; much of the information and insight that is needed to design a better system is not available until the existing system truly is operating as it was designed to operate.

The approach outlined in the text, involving sampling-based monitoring of care processes (rather than outcomes), is directly analogous to the sampling-based monitoring of processes currently used in other industrial programs of continuous improvement. I would add that in the industrial programs in general the information from samples is not used to identify causes of variation; it is used, instead, to indicate when it would be economical to initiate inquiry into causes of the variation. For the process of searching for assignable causes of variation costs time, money, lost productivity, and often also pride and workplace harmony. For these reasons, such inquiries are kept to a minimum. Statistical sampling of processes (not merely records; the sampling should produce data not otherwise recorded) provides the basis for deciding when to search, and it limits the scope of where to search and
what to search for; but the identification of an assignable cause of variation (an object of repair, retraining, or disciplinary action) is never made on the basis of the sampled data, it is made only on the basis of a thorough inquiry triggered by statistical anomalies in the sample data.

There are details of Deming’s perspective that would lead to augmentations of the quality assessment program sketched in section 14.5 beyond sampling of the records by sampling of the processes to produce new data. Some of these may be worth mentioning. In the text the authors proposed review, by an in-hospital panel, of narratives of the care of individual patients. This is, no doubt, salutary, and representative of the activities of development programs in all professions. But the Deming perspective is not to focus on the sequence of processes that a unit (e.g., a patient) passes through, but rather focus on the sequence of units that pass through an identifiable process (e.g., colonoscopy). Both perspectives provide valuable information, but it is the latter perspective that enables the statistical search for evidence indicating nonrandom variation.

The rates of untoward findings should not be the basis for remedial action as suggested in the text: Deming often made the point that rates themselves do not communicate whether a system is operating at capacity. Instead, they provide raw material which epidemiologists would be well qualified to critically examine in searching for evidence of performance levels outside of system control limits. Epidemiologists would provide this service by combining rates of untoward findings with other facility-specific information, for example on demographics of the served population, caseload during the period in question, experience level of staff, etc., to assess whether an observed rate of untoward findings deviates enough from experience across other facilities to warrant an inquiry into the existence of assignable causes of variation at that facility.

These details of a program of quality improvement can be worked out once hospital administrators become acquainted with and adopt the conceptual framework of continuous improvement. There will, however, be institutional obstacles to adopting this framework, which need to be thought through. Deming’s industrial quality improvement philosophy requires close collaboration among the parties involved in ways that differ from models of confidentiality and proprietary information currently fashionable in medicine. In manufacturing-related industrial settings, part of the means to avoid expensive inspections of purchased goods (e.g., parts purchased from a supplier for further assembly) is the requirement that vendors provide evidence of quality control of their processes along with their deliveries, so that purchasers can confirm that a lot of goods was produced under suitably controlled circumstances; the goods themselves are not inspected; instead, information about the vendor’s internal processes is disclosed along with the delivery. In a hospital setting, the analogue would be providing to those concerned, patients included, a report on the degree of uniformity achieved in the processes relevant to the quality of the provided care.

Even though medical institutions are supposed to be self-policing, it is not enough to supply quality-assessment reports to the hospitals’ quality-assurance boards and government regulators, for these entities are not interested in the quality
in the classical sense of the term. They do not have a stake in the quality of care, as they do not suffer the consequences of poor-quality care. While the persons in those functions may well have the best interests of patients and society at heart, management practices are generally anchored to the interests associated with the positions involved, rather than to presumptive virtues of the people assigned to those positions. Society at large, and patients in particular, have a stake in the quality of healthcare, so they are the genuinely interested parties to whom evidence of internal quality control should ultimately be disclosed.

Administrators and regulators have a two-tiered responsibility in quality control: first, to drive the continuous pursuit of quality within systems operating as designed, and second, to rationally redesign systems operating at the limits of their capacity for better performance. It is with respect to the first of these two that assurance of performance should be provided to patients and to society at large, and it deserves note that this is not information of a professionally esoteric kind; information about the state of control of internal processes is largely non-technical and thereby comprehensible to the general public. This information does not tell patients whether their specific care will be (or was) good or not, but it can assure them that the systems that care for them are operating at capacity, that is, that the care being provided is statistically as good as can be reasonably expected of the system. On the other hand, information supporting redesign of workflows should be shared within competent professional communities, notably among administrators of similar facilities across the jurisdiction involved.

The application to medicine of the quality control methods of industry at large is complicated by the fact that medicine is a service industry (not unlike, e.g., the hospitality industry). Even though the methods pioneered in manufacturing have been successfully applied in service industries as well, banking and hotels being outstanding examples, many problems specific to service industry have been identified in these applications.

One of the most difficult problems in service industries in general is that enterprises tend to serve captive audiences; there is little pressure from distant competitors, and therefore considerable difficulty in motivating the necessary constancy of purpose necessary for continuous improvement. In line with this, there are rarely two general hospitals operating across the street from one another, and hospitals at a distance are only slightly in competition with one another.

Another problem of service industries is that they do not face elastic market demand; a service enterprise cannot expand the overall volume of business in its segment (e.g., by productivity breakthroughs that lower costs); it can at best take market share from competitors. Thus, a hospital that lowers the cost of delivering babies may take business away from other hospitals, but it is unlikely to affect the overall number of births in a given population. Improvements in the cost of child birth are not rewarded with a baby boom.

In service industries there is a tendency to sample users of the service regarding their satisfaction, while really needed for quality control is sampling of the processes that go into providing service. Just as quality control in manufacturing cannot be based on examining finished products, so also quality control in medicine
cannot be based on interviews of served recipients of care. Medical care in larger institutional settings provides opportunities for sampling of care processes, while the service processes of solo practitioners are difficult or impossible to document.

A final problem typical of service industries, and shared by medicine, is the problem of one-of-a-kind in service environments. No two hospitals have the same layout, or serve demographically identical populations, or have identical average ambulance transportation times from residential neighborhoods. As a consequence, each facility is likely to implement distinct processes, and therefore lessons learned at one facility may not be transferrable to another, and rates of error will be difficult to compare between facilities. Some service enterprises, chain restaurants and some hotel chains being prominent examples, have made great efforts to standardize facility layout and location (e.g., relative to road intersections) in order to mitigate the one-of-a-kind effect, and the results have been truly remarkable. Many diners may not think of chain restaurant food as being of ‘high quality,’ but when quality is understood in terms of eliminating nonrandom sources of variation, then it is indeed of very high quality – it is very consistently what management specifies it should be, the diners’ wishes notwithstanding. The degree to which such standardization is possible (or politically acceptable) in medicine remains to be seen.

As medicine shares with certain other service industries (e.g., education) the peculiar structure of having third-party payers cover some or most of the expense, this structure poses certain further challenges for quality assurance, notably agency conflicts and data quality (objectivity) challenges. Whereas third-party payer systems are inherently prone to shift costs, that is, charge some customers more than the true cost of their service in order to subsidize similar service to others (e.g., cost transfers between urban and rural populations, or between wealthy and poor populations, etc.), third-party payer systems tend not to generate objective cost data on the services rendered – the subsidies are hidden in the cost data, making the data not truly representative of costs under management. Without reliable data, quality assurance is greatly complicated, if not precluded outright.

Where possible, the remedy would be to separate the subsidy function from the function of rendering service, for example by having the government restrict its role to paying subsidies (and monitoring regulatory compliance) and allowing the private sector to render service (and collect geographically varying market fees). Similar separation could be accomplished between national and state/provincial governments, to a degree. Such separation of duties is called for in all aspects of management practice where the integrity of data is a concern, and it is the management analogue of the principle of separation of powers in government, whereby preventing concentration of responsibility in one branch makes collusion, concealment, and deception more difficult. The argument for separation of duties is only indirectly an efficiency argument; it is directly a transparency and integrity argument. Separation of duties is an aspect of system design intended to expose information that might otherwise be concealed or distorted, by documenting the information in the public interactions of the separated parties. This information is then available for better management toward whatever objective is socially desirable, be that efficiency, equity, availability, or quality.
Major cultural changes are required if programs of improvement in hospital-based healthcare were to be brought to the standards of service industry in general, but this should not deter taking on the mission. One reason for setting out to meet the challenges is the enormous improvement not only in manufacturing but in service industries as well consequent to the introduction of the quality control ideas in the 1920s (the time of the original work of Shewhart, Dodge, and others). And another, burning reason is the well-known and ever worsening cost crisis of modern healthcare. The authors’ gambit deserves both attention and follow-on.
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