Ten Principles for More Conservative, Care-full Diagnosis

Gordon D. Schiff, MD1,2, Stephen A. Martin, MD, EdM3*, David Eidelman, MD4*, Lynn Volk1,5, Elise Ruan1,5,6, Christine Cassel, MD7*, William Galanter, MD8*, Mark Johnson,12* Annemarie Jutel, PhD9*, Kurt Kroenke, MD10*, Bruce Lambert, PhD11*, Joel Lexchin, MSc, MD12*, Sara Myers1,5, Alexa Miller13*, Stuart Mushlin, MD14*, Lisa Sanders, MD15*, Aziz Sheikh, MD16*

*Member of expert panel

Abstract: Balancing tradeoffs between under-diagnosis (missing/delaying important diagnoses), and wasteful harmful over-diagnosis (labeling patients with “diseases” that may never cause suffering or death) represents an important current clinical and health policy issue. While often portrayed as the need to keep the pendulum from swinging too far in either direction, there is a need to view these two poles as two sides of the same coin, unified by the need for a more thoughtful, caring and conservative approaches to diagnosis.

We assembled an international panel of experts on diagnosis, primary care, patient safety, medical communication and quality improvement to create a framework for more conservative diagnostic practices to guide clinicians, policy makers, in promoting more appropriate and cost effective diagnostic approaches. Ten overarching principles emerged: the need to promote enhanced clinician modes of caring and listening, developing a new science of clinical uncertainty, rethinking ways symptoms are approached and diagnosed, maximizing conti-

M ultiple, competing spotlights currently highlight the challenges associated with medical diagnosis. From one side, the recent National Academy of Medicine report suggests every person will experience at least one serious diagnostic error during their lifetime. Research has increasingly illuminated the problem of diagnostic errors and delays as the leading cause of medical malpractice claims (1-3). Uncertain and worried, patients and clinicians seek reassurance from diagnostic imaging, laboratory tests, and referral to specialists. On the other hand, clinicians and patients are being urged to use fewer diagnostic tests, and “Choosing Wisely” campaigns focusing on overuse of costly and/or potentially harmful diagnostic testing have been initiated in nearly every U.S. medical specialty and 20 countries worldwide (4-7). Evidence increasingly shows that reflexive ordering of tests and referrals or indiscriminate screening of asymptomatic patients often fails to provide definitive explanations or generate beneficial treatments and is often more harmful than beneficial (8).

Balancing tradeoffs between under-diagnosis (missing or delaying important diagnoses) and wasteful, harmful over-diagnosis (labeling patients with “diseases” that may never cause suffering or death) is often portrayed as the need “to keep the pendulum from swinging too far in either direction” (9). This framing of the problem as a simple tradeoff misses a fundamental dynamic. Instead of a one-dimensional continuum, we see the need for an approach that views under- and over-diagnosis as two sides of the same coin, unified by the need for a more thoughtful and caring approach (Table 1). This calls for a set of overarching principles to support improved clinician and patient decision-making and education, as well as guide health policy decisions to ultimately improve health outcomes and decrease costs.

Table 1. Potential Labels for New Diagnosis Approach

<table>
<thead>
<tr>
<th>What to Call This Approach to Diagnosis?</th>
<th>“More ... Diagnosis”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conservative</td>
<td>Modest</td>
</tr>
<tr>
<td>Judicious</td>
<td>Prudent</td>
</tr>
<tr>
<td>Mindful</td>
<td>Caring</td>
</tr>
<tr>
<td>Patient Centered</td>
<td>Appropriate</td>
</tr>
<tr>
<td>Shared</td>
<td>Cautious</td>
</tr>
<tr>
<td>Listening</td>
<td>Skillful</td>
</tr>
<tr>
<td>Relationship-based</td>
<td>Smarter</td>
</tr>
<tr>
<td>Effective</td>
<td>Realistic</td>
</tr>
<tr>
<td></td>
<td>Honest</td>
</tr>
<tr>
<td></td>
<td>Rational</td>
</tr>
<tr>
<td></td>
<td>Safer</td>
</tr>
<tr>
<td></td>
<td>Optimal</td>
</tr>
</tbody>
</table>

For author affiliations, see end of text
Expanding from our previous work on principles of conservative medication prescribing (10, 11). We propose principles that apply the precautionary principle to diagnosis. The precautionary principle urges erring on the side of restraint in using new technology until we have sound evidence of benefit and long-term safety (12). We have combined this approach with core care, especially primary care, principles (care continuity, trusting relationships, good communication), and key patient safety lessons (situational awareness of pitfalls, safety nets to mitigate harm, culture to facilitate learning and avoid blame) (1, 13, 14). We assembled a diverse group of clinicians, educators, health policy and communication experts and developed the following 10 principles.

1. PROMOTING ENHANCED CARE AND LISTENING

Patients seek explanations of their symptoms to successfully resolve or manage them. They rightfully expect their concerns to be taken seriously and to receive accurate explanations (15-17). Clinicians often rely on lab testing, imaging, and specialist referrals to “rule out” serious, potentially life-threatening diagnoses and decisively identify issues for which a specific treatment could be beneficial. However, this standard paradigm—diagnostic testing to provide an exact diagnosis for suitable treatment—rests on three problematic assumptions.

First, this paradigm posits that testing is the key to making an accurate diagnosis. It shortchanges the role of patient history and physical examination, despite the fact that carefully listening to and observing patients over time often provides more valuable information than a myriad of radiological or chemical tests (18, 19). Importantly, a reductionist test-focused approach overlooks the role of the patient in “co-producing” diagnoses collaboratively with clinicians (1, 20).

Second, and more fundamentally, the standard paradigm presumes that diagnosis is the sole overriding goal. It presumes that an exact diagnosis can always will be made and that diagnosis invariably matters for selecting therapies. It also implies patients value having a technical diagnostic label more than having their concerns (stated and unstated) addressed. It ignores the fact that diagnoses often evolve over time, making diagnosis more of a process than an outcome. Finally, it suggests that the best way clinicians can demonstrate that they are taking patients and their symptoms seriously, is to order tests.

We need to go beyond the Choosing Wisely recommendations that question the value of diagnostic practices “test-by-test” and seek an integration of the best traditions of scientific medicine, patient-centered care, and shared decision-making (21, 22), to create diagnostic approaches founded on the assumption that caring and thoroughness are not synonymous with ordering tests and referrals. Using tests as shortcuts, workarounds, or substitutes for the nuanced human endeavor of diagnosis based on respectful listening and examination is a recipe for both under- as well as over-diagnosis (23).

2. DEVELOPING A NEW SCIENCE OF UNCERTAINTY

Ironically, as tests have become more precise and “precision medicine” has become major pre-occupation, there is a growing awareness and appreciation of the pervasiveness of uncertainty in medicine (24, 25). The proliferation of new imaging, genetic, and self-administered diagnostic technologies and “apps” often amplifies uncertainty (26) by identifying incidental findings, genetic “risk factors” that correlate poorly with patients health or have poor predictive accuracy especially when applied to patients/populations with low probability of serious disease. Far from providing a single, actionable “answer” for issues like headaches or back pain, this surfeit of data demands cautious evaluation and interpretation based on each patient’s context. Tests we had hoped would lend certainty, instead, have magnified diagnostic complexity and ambiguity.

Thus, we need to develop a new science and praxis of uncertainty, accompanied by a public conversation acknowledging the challenges of working under conditions of uncertainty and opportunities for learning and collaboration (25, 27). A four-pronged strategy is needed. First, clinicians need to appreciate their own and medicine’s limitations. This requires physician humility, based on better recognition of the ways uncertainty and error impact complex biologic and social systems. This prescription for modesty can serve as a starting point for enhanced situational awareness and practicing more reflective, cautious and, ultimately, conservative medicine.

Second, beyond simply becoming aware of our limitations, we need to accept uncertainty as intrinsic to our work and become more comfortable with working with uncertainty (28). However, being more aware of uncertainties can counterproductively lead to more clinician and patient anxiety and/or ordering more tests. Additionally, becoming comfortable with uncertainty should not lead to complacency, resignation, or indifference to patients’ concerns. Patient suffering and anxieties must be respected rather than handled dismissively. Thus, a third requirement is developing sensitive, caring, and effective ways of communicating uncertainty to patients. We need better language, experience, and feedback from patients
to help us advance the state of the art for discussing uncertainties. Clinicians seeking to be both honest as well as reassuring to patients will need help with recommended yet customizable language, along with time and support to foster transparently sharing uncertainty. Different patients will have different needs and desires, and we need to develop better ways to flexibly address and accommodate these varied needs.

Finally, we need more thoughtful and effective ways to operationalize our practice of uncertainty science. At the most basic level, the crafting of a differential diagnosis structurally acknowledges that a single definite diagnosis is not always possible or desirable. Physician notes, even in serious malpractice cases, often lack an adequate differential diagnosis. We need to learn how to craft and convey accurate assessments that incorporate uncertainties, especially as we open our notes to patients. Unfortunately current electronic records are becoming littered with a with a host of distracting information and tasks taking us away from this key element of operationalizing our reflecting, recording and acting on our diagnostic thinking (29). Engineering proactive, reliable follow-up and outcomes feedback is another important aspect of ensuring that acknowledgment of uncertainty is hard-wired into medical practices (26, 30, 31).

3. RETHINKING SYMPTOMS
More than half of office visits are prompted by common symptoms. Nonetheless, decades of studies have demonstrated that up to one-half of symptoms defy definitive medical diagnosis. Most symptoms are self-limiting, with 75-80% improving over the next 4-12 weeks, usually irrespective of medical treatment (32). Additionally, some patients’ symptoms meet criteria for depression, anxiety, or somatoform illnesses—diagnoses which in up to 2/3 of patients go unrecognized and untreated (33). Visits for “medically unexplained symptoms” are now the fastest growing type of medical encounter (34), many of which are rooted in social circumstances, financial problems, and stresses patients experience at home (or lack of one), work, and/or their relationships. Even when clinicians identify these “non-medical” problems, they often fall back on their more limited repertoire of tests and drug treatments (35). Caring for such patients can be frustrating, leading clinicians to be dismissive or stigmatizing. We need to move away from exhaustively trying to “rule-out” multiple rare diseases then labeling patients as “non-organic,” and toward more thoughtful approaches.

Another failure in our current approach to symptomatic patients that can lead clinicians to stray from a more conservative path is failure to accurately match symptoms to disease syndromes. Isolated symptoms are often misconstrued by clinicians (or patients searching the Internet) and inaccurately connected to unrelated incidental lab or imaging findings. For example, a clinician may misattribute a mental status change in an elderly patient to a urine specimen suggesting bacteriuria (frequently improperly collected using non-sterile methods or merely representing colonization, not urosepsis) (36).

4. MAXIMIZING CONTINUITY AND TRUST
Continuity of care is the foundation of judicious clinical practice. Without knowledgeable, trusting relationships, clinicians often resort to defensive, inadequately informed, costly, and less-productive practice styles. Health systems that maximize relational and informational continuity perform better and cost less (37, 38), and patients value having a personal clinician who knows them well. The clinical phrase “in her usual state of health” represents clinician knowledge of a patient’s baseline; a longitudinal understanding that critically informs diagnostic strategy and facilitates diagnostic restraint.

Realistically, as health care shifts toward teams, urgent care centers, shift-work duty hours, and increasing emergency department use, not every encounter will involve a clinician who has a long-term relationship with that patient. However, we can work within the evolving landscape to maximize continuity, creating models for more convenient in-person or phone access to their primary providers. When clinicians’ schedules are overbooked for months, preventing patients ready access, practices must redesign scheduling and provide needed resources that give appropriate priority to continuity.

Additionally, money matters. Continuous insurance coverage is vital to ensure ongoing rather than disrupted care. While not a panacea, universal single-payer systems that do not change coverage with shifts in employment, age, family income, or marital status, have demonstrated better care continuity (39). Financial incentives impact trust and can undermine long-term trusting relationships. If clinicians are financially incentivized to order or withhold tests, patients may find it difficult to trust clinicians’ watch-and-wait recommendations (40).
5. TAMING/TAKING TIME

Time is the currency of clinical care. While few clinicians would disagree in principle with the conservative diagnostic practices we advocate here, many would argue they simply do not have time for prolonged discussions about uncertainty, exploration of symptoms in greater detail, or exhaustive follow-up. Additionally, time is the great incubator for diagnosis. Conservative diagnosis requires carefully and skillfully weighing information as it evolves. Thus, in both the immediate clinical encounter and in the longer-term relationship, having adequate time to listen, observe, discuss, and think is a decisive factor that separates good diagnosis from under- and over-diagnosis (32, 41).

Given the limitations of time, we will need to creatively redesign care to facilitate time for clinical diagnosis. Practical strategies include more efficient delegating to other team members, re-engineering telephone and electronic communication, and developing reliable systems for monitoring patients longitudinally. Such approaches enhance operationalizing what is often the most important test—the test of time, leveraging watchful-waiting, which is a fundamental pillar of conservative diagnosis and an antidote to unwatchful-neglect that patients fear.

6. LINKING DIAGNOSIS TO TREATMENT

Both conceptually and practically, diagnosis needs to stand less alone and more in tandem with treatment. The value of diagnosis is greater for conditions with effective and specific treatments, while more limited when no therapy exists or when a diagnosis is not needed to select among treatment options. Faced with patients experiencing nonspecific back or neck pain without neurologic findings, acute upper respiratory or sinus symptoms, stable chest pain, chronic headaches, or mild head trauma, clinicians should avoid ordering tests without weighing the likelihood that the results will influence treatment decisions or contribute to (or detract from) patients’ wellbeing (8).

Diagnosis should be pursued based on the availability, effectiveness, specificity, urgency, and acceptability of a therapy. Determining the importance of a specific diagnosis entails an iterative discussion between the clinician and patient of broader management considerations, including how the patient might want to proceed given various possible contingencies and diagnoses. A patient with back pain but opposed to surgery may be better served by focused discussion and ordering physical therapy rather than pursuing imaging studies to precisely define the pain’s exact anatomical location.

7. TESTS – MORE THOUGHTFUL ORDERING AND INTERPRETING

Practicing more conservative diagnosis is not just saying “no” to tests or patients requesting them. Rather, it is about more intelligent test selection, timing, and interpretation, and using a more balanced understanding of their benefits, harms, costs, and limitations (42). Patients and clinicians need a better appreciation of the lack of rigor in approving new diagnostic tests which are not subject to the same evidence standards or regulatory hurdles required for approval of new medications. Frequently, the studies are conducted and analyzed by researchers or companies developing and selling the test, introducing conflicts and biases (43).

We often fail to fully weigh potential harms of testing (44-46) (Table 2). Whereas some harms are obvious, many are unknown, less visible, or emerge only later, perhaps on another clinician’s watch. Clinicians must consider how best to utilize diagnostic testing, considering timing, sequencing, proper performance, errors in sample collection, analysis, and interpretation, and overall marginal benefits. Test results should be viewed as only a surrogate for actual benefit (47), and testing must be used more strategically and held to a higher standard of evidence than it is currently.

8. SAFETY NETS – INCORPORATING LESSONS FROM DIAGNOSTIC ERRORS

Recent attention given to diagnostic errors might seem to argue for more aggressive defensive medicine to exclude a myriad of diagnoses lest they be missed and labeled as errors and delays (1). However, as discussed above, simply increasing testing does not necessarily result in answers and information that patients and clinicians often seek. By better anticipating the potential for specific diagnostic errors, and we can create systems to protect against these more serious pitfalls while also safely pursuing conservative diagnostic approaches in ways that are synergistic with initiatives to reduce error.

The National Academy of Medicine and others have made a series of recommendations that, if followed, could provide guidance and afford wider latitude for more cautious practice (1). Clinicians armed with focused “situational knowledge”—such as key pitfalls to avoid, red flags, and critical diagnoses for various scenarios—could be more comfortable practicing conservatively. Additionally, incorporating patient safety culture lessons related to avoiding blame, encouraging staff and patients
to speak up, learning from errors and near misses, and disclosure/apology can all support the organizational fabric to support more conservative reflexes, conversations, and practices (48, 49). Thus, understanding where safety fails and building protective safety nets allows conservative diagnosis to avoid error.

**Table 2. Potential Harms from Diagnostic Testing**

<table>
<thead>
<tr>
<th><strong>Direct Harm</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Complications from invasive tests</td>
<td></td>
</tr>
<tr>
<td>Unstable patients leaving more protected environments to undergo tests</td>
<td></td>
</tr>
<tr>
<td>Delays in initiation of urgent treatment while waiting for tests and results</td>
<td></td>
</tr>
<tr>
<td>Adverse reactions (e.g., renal toxicity and anaphylaxis) from contrast or other diagnostic agents</td>
<td></td>
</tr>
<tr>
<td>Local complications from phlebotomy and catheter access (e.g., hematoma, contamination, pain from multiple venipuncture sticks, wounds) and loss of future venous access</td>
<td></td>
</tr>
<tr>
<td>Imaging-associated cancers and other radiation harms</td>
<td></td>
</tr>
</tbody>
</table>

**Downstream Harm**

- Harm from further work-up and treatment of false positive tests (especially failure to account for poor predictive value of positive results in the context of low prior probability)
- Harm from treatment caused by over-diagnosis (i.e., diagnosis of conditions that, although correctly diagnosed, would never have caused harm or required treatment)
- False reassurance (i.e., complacency or failure to treat as result of a false negative test)
- Harm from additional testing, such as cascades after an initial false positive result or over-diagnosis
- Conveying a message to patients that promotes a culture of indiscriminate testing
- Treatment of asymptomatic risk factors with interventions that cause harm

**Harm Intrinsic to Making a Diagnosis**

- Stigmatizing labels that may outweigh any benefits of the diagnosis for a patient
- Anxiety from diagnoses that would not otherwise have been discovered or treated
- Increased burden of illness (e.g., more medication regimens, appointments, procedures, and lost work time and greater family burden)
- Distraction of clinicians’ and patients’ attention from more beneficial diagnostic activities (e.g., obtaining better history and serial exams) and treatment

* The risk for these adverse effects may be more or less frequent depending on the test, patient, or context but need to be recognized, weighed, and minimized when ordering and performing diagnostic tests.

9. **ADDRESSING CANCER – FEARS AND CHALLENGES**

Every era has its dreaded disease, which draws inordinate focus and elicits disproportionate fear. Today, that disease is cancer. Almost any symptom can be related to cancer, and cancers can present with various nonspecific symptoms, adding to uncertainty and fear. Clinicians and the media have long promoted early diagnosis and preventive screening to be able to treat cancer while it is still localized.

However, serious controversies surround screening efforts for many types of cancer, including prostate-specific antigen testing, and early detection for breast, thyroid, lung, and ovarian cancer. Issues include lead time bias; over-diagnosis of incidental, best-untreated cancers; false-positive and false-negative test results; uncertainties about the value of treatment; and questions about the marginal benefits of early treatment. Not only are these issues complex and difficult to explain to non-expert patients, but data are often inconclusive or conflicting.

As with enhancements in how we understand and communicate uncertainty, we will need to change the ways we think and talk about cancer (50). We will need to help patients realize that in one sense, every cancer diagnosis is “delayed” - we actually never detect the first abnormal cancer cell mitosis. More importantly, we must support patients in thinking about cancer with a better understanding of the toll imposed by adverse consequences of false positive tests and over-diagnosed cancers, helping them better appreciate the need for striking a balance between treating the few with harmful cancer and avoiding harm to the many without. We must also continue to emphasize prevention and carefully evaluate patients and their risks to sort out who can best be approached conservatively.

10. **DIAGNOSTIC STEWARDSHIP – TRANSFORMING THE ROLE OF SPECIALISTS AND EMERGENCY DEPARTMENTS**

One theme of conservative practice is discouraging indiscriminate and inappropriate use of specialist referrals and the emergency department. However, both can positively contribute by leveraging their strategic knowledge and playing stewardship roles. Specialists can provide guidance and reassurance that testing is not always required (7, 40). They could help provide safety nets (e.g. triage consultations, rapid electronic second opinions), safe harbors, legal protections for both the patients and clinicians, and counseling for patients whose diagnosis may have been initially, but not negligently missed or delayed. Emergency department clinicians can
work with primary care clinicians to help reduce unnecessary emergency department visits while helping expedite truly urgent evaluations.

More profoundly, specialists and emergency department clinicians must help construct the foundations of conservative diagnosis by showing in practice and providing evidence to guide optimal real-world testing strategies for both acute/urgent and chronic symptoms in the context of low probability serious disease, critically weighing therapeutic alternatives.

**CONCLUSIONS**
Achieving more judicious use of diagnostic testing and referrals requires thoughtful redesign of care at the individual patient encounter level, as well as systemic and policy approaches to promote and support these principles. Properly designed, practical safety nets can both protect the safety and quality of diagnosis as well as enable more conservative practice (Table 3). Efforts to improve diagnosis must center on doing the right thing for the right reasons; efforts are ill-served when cast simply as holding down cost (40). These principles can help elevate the conversation and restore the coproduction of good diagnoses by doctors and patients to its sacrosanct place in medical care.

### Table 3. Practical Safety Nets to Enable Practice of Conservative Diagnosis

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
</table>
| A. Continuity, trusting relationships | To facilitate “knowing” patients  
Ensure reliable follow-up |
| B. Shared understanding with patients regarding confidence vs. uncertainties in working diagnosis | Avoiding conflicts; assuring patient buy-in and trust that their interests supersede cost conflicts/considerations |
| C. Clinical follow-up safety nets | Communication and resolution programs for addressing errors |
| D. Administrative/HIT follow-up safety nets | Contingency planning to educate patients regarding red flag symptoms warning of potential worsening and/or misdiagnosis |
| E. Second opinions | Awareness of potential disease/symptom specific pitfalls; fail-safe mechanisms to safe guard against |
| F. Flexibility to deviate from conservative guidelines when clinically warranted | Low barriers to re-access care if needed |
| G. Culture and mechanisms that encourage and facilitate patients to question their diagnoses | Scheduled “check-ins” (visits, calls, emails) to assess course and response to treatment(s) |
| H. Protections against unreasonable malpractice claims/fears | Proactive systems for monitoring patients and ensuring course consistent with diagnosis |

The preceding statement outlining principles of conservative diagnosis was developed by an international team of clinicians, safety and policy experts, and researchers who participated in a series of calls and meetings in 2016-2018 convened by the Brigham and Women’s Hospital Center for Patient Safety Research and Harvard Medical School Center for Primary Care PRIDE (Primary Care Research in Diagnostic Errors) Project funded by the Gordon and Betty Moore Foundation.

The statement represents a consensus of the expert panel discussions and deliberations. It was iteratively developed and presented and benefited from the feedback from participants in a series of workshops where it was presented including at the Diagnostic Error in Medicine (Washington, D.C., 2015), Lown Institute Right Care Conference (San Diego, 2015), Preventing Overdiagnosis (Quebec City, 2017), International Society for Quality in Health Care (iSQura) (London 2017), Institute for Health Care Improvement National Forum (Orlando, 2017).

A summary version was published in the November 6, 2018 print issue of the Annals of Internal Medicine, and this full version is provided as a background supplement to that publication. It includes additional background, tables, and references along with more detailed discussion and case examples.

The views expressed are those of the authors and do not represent the views of the funders (Gordon and Betty Moore Foundation) nor the Annals of Internal Medicine.

We invite ongoing discussion of these issues and encourage you to send comments, suggestions or questions to the PRIDE team c/o the PI Dr. Gordon Schiff, gschipf@bwh.harvard.edu.

**Corresponding Author:** Gordon D. Schiff, MD, Brigham and Women’s Hospital, 1620 Tremont Street, 3rd Floor, Room 03-02-2N, Boston, MA 02120; e-mail, gschipf@partners.org.

**Author Affiliations:** 1Brigham and Women’s Hospital, 2Harvard Medical School, 3University of Massachusetts Medical School, 4McGill University, 5Partners HealthCare, 6Tufts University School of Medicine, 7Kaiser Permanente School of Medicine, 8University of Illinois, Chicago, 9Victoria University of Wellington (New Zealand), 10Indiana University, 11Northwestern University, 12York University (Canada), 13ArtsPractica, 14Brigham Circle Medical Associates, 15Yale University School of Medicine, 16University of Edinburgh

**Acknowledgements:** This work was supported by a grant from the Gordon and Betty Moore Foundation (GBMF). GBMF had no role in the design or conduct of the study; collection, analysis, or interpretation of data; or preparation or review of the manuscript. The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of GBMF.

**References**


