

# Standardization vs Customization: Finding the Right Balance

Christine A. Sinsky, MD<sup>1</sup>

Hessam Bavafa, PhD<sup>2,3</sup>

Richard G. Roberts, MD, JD<sup>3</sup>

John W. Beasley, MD<sup>3</sup>

<sup>1</sup>American Medical Association, Chicago, Illinois

<sup>2</sup>Wisconsin School of Business, University of Wisconsin-Madison, Madison, Wisconsin

<sup>3</sup>School of Medicine and Public Health, University of Wisconsin-Madison, Madison, Wisconsin

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**ABSTRACT**

There is an inherent tension between standardization and customization of care delivery processes. The challenge for health care systems is to achieve the right balance. At its best, standardized work can create efficiencies that generate the additional time needed for personalized care. Similarly, at its best, customization allows the people within a system to accommodate the needs, preferences, and circumstances of the unique individuals and local communities they serve. We provide examples and offer principles to decide when standardization offers the most successful path and when customization may be preferred. We believe that, in sum, the balance has shifted too far toward standardization and that a rebalancing toward customization will benefit patients, clinicians, and the health care system.

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**INTRODUCTION**

There is an inherent tension between standardization and customization of care delivery processes. Too much customization can be chaotic, time-consuming, and result in suboptimal outcomes. On the other hand, excessive or inappropriate standardization can oppress, disempower, and restrict clinicians from adjusting to their patients' and their own circumstances, also risking adverse outcomes. The challenge for health care systems is to achieve the right balance. Determining the optimal point along the continuum between these 2 approaches for any given processes requires careful consideration and should be a paramount goal of organizational leadership, standard setters, and regulators.

In this commentary, we posit that in most situations, patients receive better care when physicians and their teams have the ability to exercise professional judgment about workflow and task distribution supported by best practices of systems engineering, rather than when they are expected to perform a rigid sequence of transactions mandated by a series of well-intentioned, but distant designers. We also hypothesize that overall costs will be lower when the system is designed so that there is sufficient time for the deep work of understanding the patient, their context and preferences, and for careful medical decision making. We provide examples of when standardization will be the most successful strategy and when customization will be preferred. Finally, we offer principles to guide the optimal approach.

**Historical Context**

Concerns about the balance of standardization and customization are not new. In 1966, Donabedian wrote, "One must also consider whether, with increasing standardization, so much loss of the ability to account for unforeseen elements in the clinical situation occurs that one obtains reliability at the cost of validity."<sup>1</sup> The evidence-based medicine and guidelines movement beginning in the last 2 decades of the 20th century offered the promise of standardized treatments to improve patient

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**CORRESPONDING AUTHOR**

Christine A. Sinsky  
Vice President, Professional Satisfaction  
American Medical Association  
330 N. Wabash Ave, Suite 39300  
Chicago, IL 60611  
[christine.sinsky@ama-assn.org](mailto:christine.sinsky@ama-assn.org)

outcomes.<sup>2</sup> Over time, the push for standardization extended to how clinical care would be organized and delivered across practice sites. As an example, the Future of Family Medicine project promoted standardization by advocating that practices provide a prescribed set of core services, use electronic record systems, and employ team-based care.<sup>3</sup> The aim was to reduce unwanted variation in care processes and thereby improve outcomes, efficiency, and satisfaction. But have we gone too far?

### Transactional vs Relational Conceptualization of Health Care

Have we risked reducing health care to a series of transactions that can be delivered by any clinician, ticked off in an electronic health record (EHR), counted by administrators, reported to external regulators and standard setters, and in doing so, have we unwittingly deprioritized the relational aspects of health care?

Recent trends have shifted the health care system toward a centrally designed, transactional model,<sup>4-8</sup> and away from a locally influenced relational model of care<sup>9</sup> (Table 1). These trends include consolidation of smaller practices into larger health systems, an industrial approach to care processes (eg, “standard work”), and the rapid development and deployment of health

information technology, with associated expectations for greater mandates, measuring, and monitoring (eg, audits of record activity by role type, meaningful use measures which required specific team workflows, requirements for universal documentation of patients’ pain levels and learning styles). Many of these trends are not intrinsically detrimental and some degree of resultant standardization can be useful.

And yet we also believe that health care, at its core, is fundamentally a relational endeavor—that diagnoses are more accurate, adherence is greater, costs less, when care is delivered on the foundation of a continuous, well-supported patient-physician relationship. Likewise, we believe that stable relationships between physicians and other care team members contribute to Quadruple Aim<sup>11</sup> outcomes of better care, better health, lower costs, and greater clinician satisfaction.<sup>12</sup> If we only measure transactional aspects of care and drive toward standardization to meet these measures, we believe we risk undermining one of the core drivers of quality, cost containment, and satisfaction—relationship-centered care.

### Standardization

Consistency across clinical sites offers advantages to an organization: it provides guidance during emerging

**Table 1. Contrast Between Standardization and Customization in Health Care**

	Standardization	Customization
Conception of health care	Transactional	Relational
Conception of clinicians	Clinicians will perform better with clear standards and regulations.	Clinicians are the interpreters between the guideline and the individual circumstance and can be trusted to use good judgment in working for patient’s best interests.
Organizational approach	The approach is one of management: to regulate systems and direct individuals.	The approach is one of leadership: to optimize systems and to guide individuals.
Change management strategy	The strategy is command/control; design and deploy.	The strategy is to empower and encourage.
Management approach	Management makes top-down decisions, ideally with local input.	Management encourages local engagement; promotes agency for the teams.
Resultant culture	Culture may have elements of security as clinicians don’t have to exert judgment over standard processes, yet culture also has elements of learned helplessness, along with fear or moral distress when the standard processes don’t match the needs of the patients.	Culture is possibility-based; clinicians are empowered to embrace responsibility and creativity, and yet this requires additional cognitive work and accountability for outcomes beyond that of simply following a process.
At its worst	Oppressive; flawed standards and metrics may harm people and cause burn-out.	Chaotic, unreliable, poor quality, difficult to measure.
At its best	Improves the chance that routine and required tasks will be performed, freeing clinicians for deep thinking and relationship building.	Allows modification of care processes for people’s individual needs. Builds trust. Encourages innovation.
Example of care at its best	System-wide initiative to reduce cardiovascular events by promoting medication adherence at every opportunity (office consult, flu shot, pharmacy visit, etc).	Primary care team at satellite clinic develops a workflow that includes co-location of reception staff with nurses and MAs, allowing greater sharing of care under the supervision of the local site leadership.  Contrary to hospital rules, a husband was allowed in bed with his dying wife and to bring extended family members into the ICU. <sup>10</sup>

ICU = intensive care unit; MA = medical assistant.

health threats, facilitates the training and cross coverage of staff, allows for a more predictable patient experience, and can promote the wider adoption of efficient workflows. Improved outcomes have resulted from standardized approaches to medication administration,<sup>4</sup> use of ventilator bundles to avoid pneumonia,<sup>13</sup> protocols during an emerging epidemic, and other interventions. Similarly, patient confidence in care may increase when standards are followed.<sup>14</sup>

Practices such as lean design, adapted from manufacturing, and workflow efficiency,<sup>15-21</sup> as outlined in the American Medical Association's Steps Forward program, may guide organizational standardization with the goals of improving patient flow, scheduling, and efficiency, and with the potential of improving staff satisfaction.<sup>22,23</sup> Being explicit about care processes and task distribution ensures that standard, predictable work happens reliably, freeing up physicians and other team members to devote more of their cognitive bandwidth and energy to the unique needs of individual patients. For example, standard rooming tasks,<sup>18</sup> in-box management,<sup>21</sup> computerized order entry,<sup>24</sup> care gap closure,<sup>18</sup> and components of documentation<sup>16</sup> can be entrusted to upskilled team members, affording physicians the time needed to attend to more complex medical needs and to strengthening patient trust and relationships.<sup>12,25</sup>

On the other hand, the challenges with standardization are multiple. The standard may have been established without sufficient input from those who are directly impacted by it; no matter how the standard was derived, it may still not best serve the needs of the individual patient or clinician, or the standard may not have been necessary at all. For these reasons, judgment is needed. For example, in some clinics the exact scheduled hours are set centrally by administration, in others the total number of patient contact hours per physician are prescribed with individual choice as to how to distribute across the week, and in still others, individual physicians set their own number of patient contact hours and schedule, within bounds, with corresponding financial consequences.

### Customization

Standards are designed with the average or even worst case in mind. Yet patients, practices, and communities vary. The physician may be caught as the mediator between the standard use case that drove the design and the unique individual who presents for care. For those on the front lines of patient care, the challenge of serving both the standards and the needs of unique individuals can cause harm and dissatisfaction among patients and contribute to moral distress and burnout among professionals.<sup>26</sup>

Customization is important for the increasing number of patients with multiple comorbidities where the medical evidence does not provide sufficient tailored insights and where the patient may be far from the average case that drove the standards. Customization is also a key component of patient preference-based care,<sup>27</sup> an approach which has been shown to reduce surgical procedures, hospitalizations, and overall costs.<sup>28</sup>

There are aspects of clinic operations for which both customized and standardized approaches are appropriate. For example, with respect to scheduling, wise standardization can achieve both fairness ("A full-time nurse works 40 hours per week") while allowing for customization ("This team can meet the needs of their patients by establishing earlier start and end times 2 days per week.").

On the other hand, too much customization in clinical and workflow decisions can increase the cognitive workload for clinicians who are left to design their own individual care pathways and workflows from scratch.

### Principles

We propose 4 principles to employ when deciding between standardization and customization.

#### Collaboration

Processes and policies developed in collaboration with end users are more likely to improve compliance, promote agency, increase professional satisfaction, and achieve higher care quality. Perhaps as important as the standards themselves is the way they are developed and disseminated. Large hierarchical organizations often use top-down design and deploy strategies for standards development, implementation, and enforcement. Such an approach can leave physicians feeling like "cogs in machines," exacerbating burnout.<sup>29</sup> Actual examples of system-wide standards that thwart overall system goals can be found in Table 2. (Note that Table 2 highlights only problems that occur when the balance is too far in the direction of standardization; as discussed above, we recognize that there are many benefits to standardization when the balance is more appropriate.)

An alternative approach is exemplified by lean design, which is based on the principle that the work should be designed in collaboration with those who do the work.<sup>30</sup> For example, advanced models of team-based care have been developed by the clinicians and their teams in collaboration with health system administrators.<sup>25,31-33</sup> In addition to clinical staff, practices must also consider how to engage patients so that their perspectives and preferences are heard and respected.

System managers can look to implementation science for guidance in developing standards, as that literature discusses the need for a participatory process that builds on evidence-based best practices.<sup>34</sup> An approach in which health care managers and clinical staff collaborate to determine which processes and standards are best left to individual practice sites and which benefit from uniformity across an organization will be better for patients, clinical teams, and organizations. Some questions to be addressed when standardization is considered appear in Table 3. Health care leaders should endeavor to standardize clinical processes with humility, respect, and ample end-user input, and push only those standards that are evidence-based and/or have stakeholder endorsement.<sup>35-38</sup>

### Decision Authority

Empower the professionals closest to the patients with authority over the resources and processes in order to achieve the desired outcomes. An “empowering leadership” style that seeks frontline worker input and distributes authority may take more time in the short-run, but it can outperform a “directive leadership” approach in the long-run because it improves organizational learning, team morale, and collective problem solving.<sup>39</sup> Likewise, moving authority for clinical oversight of staff functions locally will reduce waste. For

example, central decision making at one practice prevents medical assistants from performing orthostatic blood pressure measurements, leaving this task to the physician. Yet, when oversight is moved closer to the practice, appropriate adjustments can be made based on demonstrated abilities of local staff.

### Measurement

Seek measures of customization in addition to those of standardization, and strive for measurement parsimony.

It is widely agreed that current quality measures are excessive, with calls from within both the measurement and the broader health care communities for harmonization and parsimony. The National Academy of Medicine Vital Signs<sup>40</sup> initiative identified thousands of measures used in the United States to oversee clinicians—contributing to work overload, clinical distraction, and burnout—and recommended a sharpened focus on just 15 core measures.

Measurement has traditionally relied on compliance with standardization (often reflecting a transactional conceptualization of health care). It is important to include measures that also account for customization (thereby reflecting a relational conceptualization of health care). The American Board of Family Medicine has proposed a reduction in the myriad of primary care measures to a single instrument, the Person-Centered

**Table 2. Examples of Hazards of Standardized Operations**

Organization Standard	Organizational Goals	Actual Outcome	Better Strategy
All nurse practitioners and physician assistants must work the same patient care hours, 8:00AM to 4:30PM.	Provide dependable access to care. Treat all NPs and PAs the same.	Personal circumstances (eg, childcare) may prevent some individuals from working specified hours resulting in lower morale, difficulty with recruitment and retention, and worse access to care.	Clinical sites allowed to work out coverage for specified hours and held accountable for access, resulting in greater individual flexibility, better team cohesion and morale.
On entering the exam room, the first task for physicians and staff must always be to log in to the computer.	Provide time stamp of staff activities.	Disrupts the “golden minute” at the start of the interaction, with less eye contact and lower patient and staff satisfaction.	Promote routine of “patient first, computer second.” If needed, track staff activities in other ways (eg, radiofrequency fob).
All emergency (“crash”) carts must have the same equipment and medication; no more or less.	Better manage inventory. Prevent improper use.	A woman at a rural site died after precipitous birth with uncontrolled uterine bleeding due to atonic uterus that did not respond to fundal massage. Transport time was at least 60 minutes to a hospital and there was no oxytocin or other tonic agents stocked in cart.	Identify required items for all carts, and then allow additional items based on site needs. Assure adequate training in the proper use of crash cart items (eg, ACLS, ALSO).
Medical assistants are not allowed to perform orthostatic blood pressures.	Assure quality of care. Protect the clinical domain of one role type.	Orthostatic blood pressures are not done as frequently as clinically useful; patients have reduced access to the unique skill set of their physicians (who are spending time doing orthostatic blood pressures on other patients).	Upraise the staff; allow the supervising clinical staff to determine medical assistant competency to perform orthostatic blood pressure.
All incoming patient calls are sent to a centralized call center.	Efficiency Reduce call volume for staff at clinic sites.	Continuity is disrupted and care is less personalized when patient speaks with a nurse with whom they have no relationship; patients may be routed to someone other than their personal physician even when that physician would have seen them for their need.	Allow individual units to determine how best to handle calls for their unit—locally or via a back-up central call center.

ACLS = advanced cardiovascular life support; ALSO = advanced life support in obstetrics; NP = nurse practitioner; PA = physician assistant.

Primary Care Measure, which assesses care across 11 domains including access, continuity, comprehensiveness, coordination, advocacy, and context. Representative questions from that instrument include: "In caring for me, my doctor considers all factors that affect my health" and "The care I get takes into account knowledge of my family."<sup>41</sup>

One of the largest initiatives to standardize and measure quality is the Quality and Outcomes Framework (QOF) launched by the United Kingdom's National Health Service in 2004. Focused on primary care, the QOF established 165 metrics against which the performances of the practices were audited and financially rewarded or punished. After 15 years, the QOF showed improvements in data collection and disease management strategies, but it had no effect on premature mortality<sup>42</sup> and it disrupted therapeutic relationships. After billions of pounds invested, Northern Ireland, Scotland, and Wales have dropped the QOF; England has scaled it back substantially.

Likewise, in the United States after several decades of experience, pay for performance has not lived up to initial expectations of improved health outcomes and lower costs.<sup>43</sup>

For clinicians and staff, the added burden of such documentation<sup>44-47</sup> contributes to decreased job satisfaction,<sup>48,49</sup> with clinicians reducing work hours or considering a change in career in response.<sup>50</sup> Increased documentation requirements tempt clinicians to multitask and to complete documentation during patient encounters,<sup>51</sup> which can significantly decrease the quality of both the documentation and the care provided. Meaningful Use measures for electronic health record adoption contained many measures requiring

documentation (eg, "implement one trackable clinical decision support rule") that clinicians found to be of little use.<sup>52</sup>

### Variation

Not all variation is bad. Variation in process measures can signal the need for greater standardization or alternatively, be a sign of appropriate customization.

Some variation in process measures will identify opportunities for improvement. For example, if one primary care site has thrice the number of prescription refill requests per chronic illness medication than another site, this may represent an opportunity to educate the clinicians and staff about the value of a systems approach to prescription renewal (ie, standard process of providing 90 days plus 4 refills for stable chronic illness medications)<sup>17</sup> and offer support to the team in this process improvement implementation.

At other times variation in care will identify appropriate customization. For example, a practice with a high percentage of office workers who commute to work past the clinic site may find that early morning hours are popular with their patients, whereas a practice with a high percentage of teachers may find the need to have more late afternoon appointments.

### CONCLUSION

A recent trend, particularly in large health care organizations, is toward standardization of clinical policies and care delivery. The hope is that such standardization will result in greater reliability, improved efficiency, and better outcomes. Yet, standardization can come into conflict with customization, and the

**Table 3. Questions to Address Before Disseminating Organization-Wide Practice Standards**

Domain	Question	Sub-Questions
Problem clarification	What problem are we trying to solve with our standard?	How important is it to address this issue? What are the root causes of this problem? Are the problems localized or generalized? What is the evidence that the proposed standard is effective?
Collaboration	Have we included front-line clinicians in the development of the standard?	Has there been sufficient input from each clinical unit that will be impacted by the standard? How are the various units working to improve this issue—what innovative ideas do they have? What do individual sites or teams see as potentially beneficial improvements? Has the standard been pilot tested with input from those impacted? Is there agreement that a system-wide set of standards is needed? How will we encourage local customization and evaluate its impact?
Consequences	Have we considered unintended consequences?	What are the potential harms to patients, teams and the organization from implementing the standards?
Resources	Do we have sufficient resources to design, implement, and evaluate the impact of the standard?	How difficult will it be to gather the evidence to design the standard? Does the organization have the capacity to implement it? Do we have valid metrics for subjective as well as objective outcomes? Does the organization have the capacity to evaluate the full range of benefits and harms of implementing the standard?

values of individual agency, professional autonomy, and relationship-based care. At its best, standardized work can create efficiencies that generate additional time for more personalized care. Likewise, at its best, customization allows the people within a system to accommodate the needs, preferences, and circumstances of the unique individuals and local communities they serve. In summary, we believe that over the past 2 decades the balance has shifted too far toward standardization and that finding a right balance with customization will benefit patients, clinicians, and the health care system.

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**Key words:** customization; standardization; burnout; administrative burden; quality measurement; transactional; primary care issues: clinician-patient communication/relationship; teamwork; leadership

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