

Right Care 4



Levers for addressing medical underuse and overuse: achieving high-value health care

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The preceding papers in this Series have outlined how underuse and overuse of health-care services occur within a complex system of health-care production, with a multiplicity of causes. Because poor care is ubiquitous and has considerable consequences for the health and wellbeing of billions of people around the world, remedying this problem is a morally and politically urgent task. Universal health coverage is a key step towards achieving the right care. Therefore, full consideration of potential levers of change must include an upstream perspective—ie, an understanding of the system-level factors that drive overuse and underuse, as well as the various incentives at work during a clinical encounter. One example of a system-level factor is the allocation of resources (eg, hospital beds and clinicians) to meet the needs of a local population to minimise underuse or overuse. Another example is priority setting using tools such as health technology assessment to guide the optimum diffusion of safe, effective, and cost-effective health-care services. In this Series paper we investigate a range of levers for eliminating medical underuse and overuse. Some levers could operate effectively (and be politically viable) across many different health and political systems (eg, increase patient activation with decision support) whereas other levers must be tailored to local contexts (eg, basing coverage decisions on a particular cost-effectiveness ratio). Ideally, policies must move beyond the purely incremental; that is, policies that merely tinker at the policy edges after underuse or overuse arises. In this regard, efforts to increase public awareness, mobilisation, and empowerment hold promise as universal methods to reset all other contexts and thereby enhance all other efforts to promote the right care.

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Introduction

In this final paper in the Right Care Series on medical underuse and overuse,^{1,3} we address two complementary approaches to achieving the right care: so-called bottom-up approaches, whereby patients, clinical professionals, and system leaders take a proactive lead with little interference from managerial authorities; and so-called top-down policies, which have arisen as governments, medical societies, or private third-party payers face the challenge of improving the safety and quality of health care amid growing pressure to control spending.⁴ Additionally, we suggest a more far-reaching perspective than is typical of micro-meso level reform initiatives, that includes a longer-term strategy for cultural change, which has been scant to date.⁵ In 2014, Dickson and colleagues⁶ outlined principles and strategies to accelerate the scale-up of high-value interventions known to be underused. We will not retrace those steps in detail, and instead focus our attention on remedies for overuse—a side of the equation that has received less attention to date. Panel 1 contains definitions of key terms used in this Series paper.

Setting the context: being clear about what we want to achieve

Most countries across the economic development spectrum aspire to high-performing, universally accessible health-care systems. The shared challenge is ensuring the right care is received by the right patients, in the right setting, at the right time, at the right cost.

Key messages

- Because overuse and underuse are so deeply entrenched in contemporary medical care, and because the harms are so considerable, efforts to remedy these issues are a moral imperative and a political duty.
- Achievement of universal health-care coverage is a moral imperative and has been adopted as a target under the UN Sustainable Development Goals in 2015. Focusing more of the world's attention towards redressing low-value care now becomes an urgent task. The fundamental ethical, economic, and political challenge arising from poor care is that as long as pooled funds are devoted to low-value care, the potential for health gain elsewhere in the system is unnecessarily restricted.
- Although no perfect solutions exist for improving the quality of health care, health technology assessment and other priority setting approaches have evolved to play a central role in determining value. In this Series paper we investigate a wide range of further interventions and policy levers that, if used appropriately, could lead to important improvements in professional practice and patient outcomes.
- Appropriate involvement of patients, community, and civil society organisations—supported through information sharing, evidence-based shared decision making, and broad public engagement—could help improve the perceived and real acceptability and legitimacy of determining the value of health-care interventions.
- Participation by these groups is essential for the success of any remedy to overuse or underuse.
- Clinical professionals and professional associations have a key role to play in championing robust guideline development and implementation processes, filling evidence gaps with quality clinical research, and leading or participating in efforts to shift from low-value to high-value health care.
- Freeing the resources from low-value care creates new opportunities for redressing underuse within the same budget envelope, by extending care to the non-covered, reducing cost-related access barriers, and including services previously displaced by lower-value resource allocations.

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Panel 1: Glossary of terms

Underuse

Failure to deliver a service that is highly likely to improve the quality or quantity of life, that represents good value for money, and that patients who were fully informed of its potential benefits and harms would have wanted

Overuse

Provision of a service that is unlikely to increase the quality or quantity of life, that poses more harm than benefit, or that patients who were fully informed of its potential benefits and harms would not have wanted

Right care

Care that is tailored for optimising health and wellbeing by delivering what is needed, wanted, clinically effective, affordable, equitable, and responsible in its use of resources

Low-value care

An intervention in which evidence suggests it confers no or very little benefit for patients, or risk of harm exceeds probable benefit, or, more broadly, the added costs of the intervention do not provide proportional added benefits⁷

High-value care

An intervention in which evidence suggests it confers benefit on patients, or probability of benefit exceeds probable harm, or, more broadly, the added costs of the intervention provide proportional added benefits relative to alternatives

As the previous papers in this Series¹⁻³ emphasise, many health systems that provide near or universal health-care coverage (UHC) face a dual challenge: the underuse of high-value services, and the overuse of no-value or low-value health-care services. With UHC adopted as a target under the UN Sustainable Development Goals in 2015, more of the world's attention will now focus on delivering the right care—not only in countries making the first steps towards UHC, but also in those that have been engaged in the process for some time.

Interpretations of UHC vary. As previously reported,⁸ these interpretations include publicly funded and provided universal, free, or affordable public health and curative services;⁹ mixed funding or mixed provision of services by the public and private sectors; UHC plans that would reduce coverage content to minimum-benefits packages or alternative systems of stratified health-care delivery; and other UHC plan structures that would primarily identify coverage with market-based or private insurance-based decision making. Furthermore, some of these definitions in practice are not the same as health care for all, because the aim is not necessarily to continually expand coverage to enable care for everyone, and in fact can present barriers to it.⁸ For example, some approaches, such as tiers of differing benefit packages for rich and poor

individuals, can risk maintaining or worsening access barriers as costs and corporate profits expand.

The WHO definition of UHC is the widely accepted framework for understanding UHC: UHC is defined as ensuring that all people have access to needed promotive, preventive, curative, and rehabilitative health services, of sufficient quality to be effective, while also ensuring that people do not suffer financial hardship when paying for these services.¹⁰ We believe this definition should be one of the first guiding moral principles used when applying the proper levers for achieving high-value health care. Achieving optimum delivery of health care for the optimum health of populations is hard to imagine without considering this definition.

The fundamental ethical, economic, and political challenge arising from this situation is that as long as pooled funds are devoted to low-value care, the potential for health gain elsewhere in the system is unnecessarily restricted. This issue is the thrust of this Series paper. To maximise these health gains, all health systems must determine the efficacy of a given health service (can it work in principle?), effectiveness (does it work in practice?), technical efficiency (can it be produced at lower resource cost?), cost-effectiveness (is it the least expensive way to achieve an outcome, such as increasing health-related quality of life?), and allocative efficiency (is the outcome worth it compared to everything else that we can do to improve wellbeing generally, for people who use and pay for the intervention?).¹¹ Focusing on care that is clinically effective, and produced in a way that is technically efficient and cost-effective, will make possible both gains towards UHC (by freeing up resources) and increase the gains achieved by investing health-care resources where they can have the greatest effect. Concentrating on allocative efficiency acknowledges that wellbeing, rather than delivering some quantum of health-care services, is the goal of health systems. Before we discuss various potential remedies to underuse and overuse, it is useful to outline a set of overarching principles, which ought not be heavily contested, and serve as a backdrop for the reform levers, as shown in panel 2.

Learning from past experiences

Attempts to remedy underuse and overuse have been ongoing since the mid-1970s with the Blue Cross Blue Shield Medical Necessity Project to today's Choosing Wisely campaigns.¹⁴⁻¹⁸ Many of these programmes have been plagued by barriers related to their acceptance and implementation. Factors contributing to these barriers range from a general lack of systematic priority setting (eg, reliable, evidence-based administrative mechanisms to identify and prioritise technologies and practices that are both clinically effective and cost-effective¹⁹) to the clinical, social, and political challenges of identifying winners (services being underused) and losers (services being overused). As we discussed in papers 1 and 3^{1,3} of

this Series, one major driver of overuse is delivering a service to more and more patients who lie outside of the population for whom the service is clearly beneficial (so-called indication creep). When that service is targeted as being overused, clinicians might resist efforts to restrict use if they believe the service might be removed completely, rather than limited to the appropriate populations or clinical indications.²⁰ Although some services should not be covered at all (eg, vertebroplasty²¹), usually a better clinical definition of the patient subgroups that will and will not benefit from any given intervention is needed. This more nuanced understanding, together with an acknowledgment of grey zones of uncertainty, has bolstered support for contemporary efforts at optimising appropriate care.²²

Policy makers must choose their methods carefully so as to arrive at a theoretical midpoint of appropriateness between the tails of underuse and overuse. Levers that target underuse can easily have the unintended consequence of exacerbating overuse and vice-versa. For example, more than a decade ago efforts were made in numerous countries to increase testing for vitamin D deficiency in primary care. In Australia, testing rapidly gained popularity with a 4800% increase over 10 years, much of which was clinically inappropriate and at a cost that could have achieved much greater health benefits if spent elsewhere. Furthermore, in 2014 Bhatia and colleagues²³ observed that efforts to decrease hospital admission rates for patients with heart failure led to increases in repeat emergency department visits and hospital admissions after previous emergency department discharge. Such examples show that the quest for appropriate medical intensity, and the consequences of overestimating or underestimating such intensity, are ongoing challenges.

With these challenges and other considerations in mind, we can begin to compile a list of potential remedies, noting that no single lever is a universal remedy and many have only a small (albeit growing) evidence base as to their effectiveness.²⁴ As we will highlight in this section, achieving the right care will require levers targeted from the patient level up to the government policy maker level, and all require careful attention to contextual factors. A key element of efforts to address overuse will be the prospective evaluation of levers used, either before widespread adoption or as part of a broad rollout. Cluster randomised trials and interrupted times-series could assist with understanding benefits and possible harms, cost-effectiveness analysis could assist with appreciating value-for-money considerations, process evaluations could assist with understanding how and why levers achieve their goals (and the implications for adaptations that can be made for local contexts without jeopardising the effectiveness of the strategy), and qualitative studies can assist with understanding stakeholders' views and experiences. Constant monitoring and evaluation is equally important to ensure that levers continue to achieve the desired goals,

Panel 2: Background principles that underpin reform levers to remedy underuse and overuse

First principles:¹²

- Citizens of all countries value optimum wellbeing
- Universal health coverage that ensures effective and affordable health care for all is one important means to this end
- Health-care professionals are morally committed to improving the health of their patients and they, alongside system leaders and government policy makers, should be morally committed to the health and broader wellbeing of communities and nations

Collectively, health systems must:¹³

- Get the right—effective and cost-effective—care to the right patients in the right setting at the right time
- Be affordable for patients and consumers, employers, and tax payers
- Maximise the number of people with access to effective and affordable health care that meets their needs

Specific components (individual services, devices, or drugs) must:¹³

- Be safe (ie, not do harm)
- Be effective
- Be cost-effective
- Be valuable compared with alternative expenditures
- Be wanted by informed patients

In a transformed health system, patients can expect to:¹²

- Have access to effective and affordable care that meets their needs
- Be informed and involved in choices about their care
- Be protected from commercial interests acting contrary to their health needs

In a transformed health system, clinicians can expect to:¹²

- Have the time they need to care for their patients
- Make clinical judgments in the best interests of their patients and of the broader community from which their patients are drawn
- Feel supported by health, political, and legal systems when they do so

both alone and in combination with other levers. Although policy makers work under many institutional constraints, face considerable interest-group pressure, and juggle competing values, research evidence can and should be a key input regarding decisions about whether to introduce, scale-up, adapt, adjust, or stop using a lever.²⁵

Levers through which high-value health care could be achieved

Patients, community, and civil society organisations

Democratic engagement is both an intrinsic value and a crucial lever for change. Patients and the wider public should be involved in the effort to achieve the right care

	Definition	Examples, including evaluations (system context most suited)
Delivery arrangements		
Matching allocation of supply-sensitive resources (such as hospital beds and health-care labour) to meet population needs	Certificates of need (wording varies between countries) are principled such that the construction of health-care facilities (eg, new hospital beds) avoids excess capacity and supplier-induced demand for hospital-based services. Most countries regulate the number of physicians and other health-care professionals, often through subsidised training. Use of Six Sigma, the lean production method, and other methods to improve process efficiency and reduce waste, allowing excess capacity to be cleared or allocated to reduce underuse.	²⁷ (All)
Include inappropriate use recommendations in CPGs	Guideline developers are encouraged, when appropriate, to specify recommendations against the use of specific practices, technologies, and pharmaceuticals (including for patient subgroups) when formulating guidance. However, the evidence on which to base definite do and do-not-do recommendations is often scarce.	Do-not-dos ²⁸ (All)
Development of appropriate-use criteria with measurement	Evidence-based, consensus-driven development of appropriate-use criteria aid in articulating the patient populations for whom any given practice is high-value vs low-value. These criteria assist clinicians at the point of care (including via HITs); feed in to (and from) CPGs; facilitate SDM; direct indication-specific payment parameters; and set the groundwork for measurement of high-value and low-value care in routinely collected datasets.	²⁹⁻³² (All)
Audit and feedback	Audit and feedback includes a summary of clinical performance of health care over a specified period of time aimed at providing information to health professionals to allow them to assess and adjust performance. A Cochrane systematic review reported a 4.3% increase in health-care professionals' compliance with desired practice, which could be as much as a 16% increase if baseline adherence is low and key design features are used. Provider level reporting and feedback has shown success even when it was not public as seen in Canada in the case of cardiac care revascularisation and harmonisation of clinical practice for caesarean section in Belgium.	³²⁻³³ (All)
HIT and EHR	HIT and EHR now include decision tools, clinical reminders, cost data, pharmacy records, and outpatient data—all of which could be used to restrict the use of marginally effective medical interventions, ranging from real-time flagging to improved auditing processes.	EHR flags (All)
Education and other support for patients and citizens regarding effective self-management and SDM	Many treatment choices patients face are preference sensitive in that each choice offers a different set of potential benefits and harms. ^{34,35} Excellence in communicating evidence-based benefits and harms in the SDM process can reduce overdiagnosis, overtreatment, and undertreatment, and align informed patient preferences with treatment choices. ³⁵ This process benefits from the use of patient decision aids.	³⁶⁻³⁸ (All)
Education and other supports for professionals about SDM, guideline implementation, and high-value care delivery	Several high-quality reviews found that educational materials, educational meetings, educational outreach visits, local opinion leaders, tailored interventions, audit and feedback, and computerised reminders had beneficial effects on optimisation of clinical practice. The effect sizes found for each of these interventions are similar, but have large variability, suggesting that the probable effects of interventions vary in relation to the degree to which the causal mechanisms of action for the intervention address the specific barriers identified. The variability also reinforces the importance of diagnosing the underlying cause of why low-value care is being used or why high-value care is not being used and then, on the basis of the diagnosis, selecting from the array of candidate strategies and iteratively refining, tailoring, and combining them in a way that maximises the effect of efforts to optimise clinical practice.	²⁵ (All)
Financial arrangements		
Complete removal from coverage schedules	For some technologies or practices, the evidence for safety and effectiveness is convincingly negative yet the practice persists. In these instances complete removal from funding schedules might be appropriate.	Vertebroplasty ³⁹ (FFS; global budget)
Tighten or restrict indications associated with coverage or reimbursement	Often evidence mounts about the population subgroups who achieve the most, and least, benefit from particular technologies or practices. Reimbursement indications can be tightened to target those with the greatest capacity to benefit. Also, frequency rules have the effect of permitting a set number of tests or treatments in a given timeframe.	Vitamin D tests; USPSTF age categories (FFS; global budget)
Reduction in third party payment due to technological advances	In non-health markets, when technology delivers on its promise and becomes safer, faster, and easier to use, the reduction in the cost of supply can drive the price down in response, provided the barriers to entry are few. Such cost reduction rarely occurs in the health-care sector, but some examples are appearing.	Cataract surgery ⁴⁰ (All)
Partial reimbursement or coverage (sits within value-based insurance designs)	For a practice known to deliver less value than its comparators (albeit still with some benefit in a subgroup of individuals), the level of reimbursement or coverage can be tiered in accordance with the anticipated health outcome. ⁴¹ For example, patients could be required to pay the full cost of a low-value practice if they choose it when a better-value alternative is available. Supplier-induced demand can raise ethical challenges here.	Arthroscopy for osteoarthritis (FFS)
Reference coverage to rate of least costly provider (meeting quality standard)	In the USA particularly, wide variation exists in the cost structures between provider institutions for the same or similar service. The payer agrees to cover the fee structure set by the least costly provider (whereby quality of outcome is matched). Clients are permitted to use more costly providers but must pay the difference.	VBID projects ⁴² (FFS; diagnosis-related groups)
Reference coverage to rate of least costly alternative for given condition	For a given condition multiple treatment options might exist that deliver similar health outcomes (ie, one or more treatments is equivalent or non-inferior to a comparator) yet costs vary for each. Coverage can be referenced to the least costly alternative. In cases whereby one treatment is deemed to be not inferior to the main comparator, no basis exists in terms of health outcomes (safety profile included) to justify a higher price, unless cost are offset as a result of a different method of administering the proposed treatment.	USPSTF ⁴³ equivalence or non-inferiority driven cost minimisation examples in pharma ⁴⁴ (FFS)
Sunset clauses (coverage with evidence development)	In cases whereby a health-care intervention has uncertain effectiveness, and insufficient evidence exists for decision making (ie, substantial uncertainty exists) funding could be guaranteed only for a set time period and, where appropriate, be conditional upon compulsory patient enrolment for evidence generation.	^{14,45} (All)

(Table continues on next page)

	Definition	Examples, including evaluations (system context most suited)
(Continued from previous page)		
Restricting later-line therapies from creeping to earlier phases	Appropriate sequences of therapy are specified to ensure later-line treatments do not inappropriately move to earlier phases in the treatment algorithm. Achievable through FFS coverage levers and encouraged through accountable care arrangements, which includes the reduction of unproven off-label usage.	Multiple treatment options for obstructive sleep apnoea ⁴⁶ (All)
Directed displacement or concurrent specification: removal of an item from funding when any new practice or technology is first funded	Innovation met with exnovation: direct comparisons to be made between the incremental benefits associated with the new programme and the incremental benefits associated with those programmes that must be cancelled or reduced to generate the additional resources required. Such directed displacement is particularly pertinent in fixed budget models of health care, whereby the concept of one in, one out can more readily be considered explicitly. Opportunity cost is ubiquitous and thus exists in apparently uncapped systems, but the feasibility of making and acting upon such direct comparisons remains to be shown.	Programme budgeting marginal analysis examples ⁴⁷ (All)
Reimbursement only for guideline adherence	Coverage is conditional upon clinicians adhering to appropriately endorsed practice guidelines. Any practice deviation is only covered once judged before a panel of peers as acceptable deviation. Such an approach relies on electronic systems for documentation of clinical activities	Pre-authorisation or post-hoc judgement (All)
Infrastructure for guideline production or implementation and for HTA and HTRA	Guidelines and HTA and HTRA are effectively public goods that can be used by all players in a health system to address underuse and overuse of health care.	⁴⁸ (All)
Global budget with pay-for-performance, risk sharing, or bundled payments	Global (eg, capitated) and bundled (eg, episodes of care) payments realign incentives away from volume (FFS) towards quality of outcomes. Concomitant risk or profit sharing adds further incentives for providers to achieve positive outcomes for their patients efficiently (ie, implementing high-value care).	^{49,50} (All)
Governance arrangements		
Revising diagnostic criteria and thresholds	As a countermeasure to overdiagnosis, which might include revisions to treatment recommendations based on risk profile of treatment vs no treatment, and prognosis.	Many cancers (All)
Compulsory review of all technology, however introduced	Occasionally, technologies enter the system through atypical routes thus circumventing regular assessment entry processes (eg, charitable donations, manufacturer samples). Although initial outlays can be low, future resource implications in training, maintenance, consumables, and staff time can be substantial. All technologies to be introduced (by any avenue) should be subject to standard HTA review and decision processes, ensuring they represent high value. Innovations in surgery might also fall under this rubric.	Da Vinci robots ^{34,45} (All)
Restrict providers to centres of excellence	High-volume specialist providers might achieve superior outcomes to low-volume providers, which can be an argument for restricting reimbursement to centres of excellence. Trading off equity of access is a consideration.	Lung transplantation ⁵¹ (All)
Stakeholder engagement	Stakeholder engagement can focus on creating the will to address underuse and overuse and the process can give explicit voice to citizens, patients, and providers committed to achieving high-value health care. Different members of the public or patient group representatives can be involved in practically any stage of HTA and coverage decision processes—eg, the design of scoping documents; participation in evidence appraisal committees as members or by providing information on living with conditions in question; or board membership, contributing to the shaping of broader policy and underpinning value judgements	⁵² (All)
Changes to who has policy, organisational, commercial, and professional authority to address underuse and overuse	Policy authority can be about who is covered, the services they receive, and the cost-sharing these individuals face. Organisational authority can be about whether accreditation is required and what it addresses, among other topics. Commercial authority can be about licensing or registering, pricing, marketing, selling, and purchasing products and services. Professional authority can be about training, licensure, and continuing competence requirements.	(All)
CPGs=clinical practice guidelines. SDM=shared decision making. HIT=health information technologies. EHR=electronic health record. FFS=fee-for-service. USPSTF=US Preventive Services Task Force. VBID=value-based insurance design. HTA=health technology assessment. HTRA=health technology reassessment.		
Table: Policy leverage options available for system leaders and government policy maker		

not only because they are both the recipients and ultimate payers, but also because actively engaging these individuals can increase legitimacy of efforts to determine the relative value of various investments in health care, from infrastructure to specific services that are covered. Three principal methods of involving patients and the public are as follows: shaping environments that help reduce demand for low-value services through adequately informed consumers; effective patient engagement in clinical decision making to maximise value (especially when care is preference sensitive); and public engagement to improve priority setting at the highest policy level.

There are many reasons to involve patients and the public in decision making. First, expectations or demands from uninformed or misinformed patients can result in pressure on clinicians to provide low-value care. This pressure is exacerbated by direct-to-consumer marketing.²⁶

Additionally, hospitals frequently exaggerate the medical utility of advertised services, such as proton beam therapy for prostate cancer. The provision of evidence-based information from trustworthy organisations that have no conflicts of interest is especially crucial in such settings (table).

Second, evidence-based shared decision making (SDM) between patients and clinicians is important on both clinical and ethical grounds. Many treatment choices patients face are preference sensitive in that each choice offers a different set of potential benefits and harms.^{34,35} Excellence in communicating evidence-based benefits and harms in the SDM process can reduce overdiagnosis, overtreatment, and undertreatment, and align informed patient preferences with treatment choices.³⁵ This process benefits from the use of patient decision aids. A 2011 Cochrane review^{36,37,53} showed that well informed patients

are less likely to choose to undergo surgery, in favour of less invasive procedures, although this is not always the case.⁵⁴ However, even if less care is not always the result of SDM, broader acceptance of remedies for overuse among patients and the public is crucially important, given the threat of rationing that often looms in the background of limit-setting decisions: SDM can ensure that decisions are made with, and not against patients.

Third, patient and public engagement is widely regarded as useful at the policy level, although robust evaluations about its benefits are rare.⁵⁵ Many countries increasingly involve patients and the public in health technology assessment (HTA) and coverage decisions. Commonly cited rationales focus on incorporating shared values, improving the legitimacy or acceptability of policy, and disseminating knowledge about decisions and processes.⁵⁵ However, despite considerable enthusiasm among policy makers for public and patient involvement, no consensus appears to exist about the priority among these rationales, and there is no consensus about which members of the public should be involved in which processes, the weight these individuals should have in influencing decisions, and how potential conflicts of interests should be addressed.⁵⁵ Although public and patient involvement in decision making has clear potential, evidence that public engagement lives up to the rationales advanced for it is required.⁵⁶

Clinical professionals and professional associations

Clinical professions must engage in robust, evidence-based guideline development and implementation. Clinical practice guidelines (CPGs) are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.⁵⁷ The majority of CPGs are developed by medical professional organisations, government agencies, and non-profit organisations. When guideline recommendations are developed through a structured, evidence-based process and applied by clinicians accurately, the expected effect would be an increase in the use of appropriate services and reduction in the use of inappropriate or unnecessary services, thereby improving outcomes, and potentially reducing net spending.

Several studies have assessed the impact of CPGs, and systematic reviews of these studies have generally concluded that CPGs improve both process and outcomes of care, with substantial variability in the magnitude of these improvements.^{58,59} Although some results are encouraging, others are not,²² and the evidence also strongly suggests that considerable variation exists around the point estimates, which contain clues as to where to focus remedial efforts. For example, audit and feedback offers an average 4·3% improvement in adherence to the guidelines, but an upper range of 16% when key considerations are addressed.⁶⁰ CPG implementation strategies must be customised to the individual guideline and clinical conditions, with attention to the barriers to

change identified in each context.^{25,61} Overall, the evidence shows that none of the approaches for transferring clinical guideline recommendations to practice is effective across all possible situations.⁶² Additionally, patients with multiple comorbidities can trigger recommendations from multiple CPGs, without providing clear guidance on how best to prioritise the interventions, potentially leading to overtreatment.⁶³

Perhaps the most important limitations to the potential for CPGs to reduce both underuse and overuse are the substantial gaps in evidence on which to base recommendations, biased evidence, and biased guideline producers. A review of 16 CPGs from the American College of Cardiology⁶⁴ showed that only 314 of 2711 recommendations (median 11%) are classified as level of evidence A (ie, multiple randomised trials or meta-analyses), whereas 1246 (median 48%) are level of evidence C (ie, expert opinion, case studies, or standards of care). Moreover, many guidelines offer advice of questionable value to patients, as a result of industry influence.^{65,66} The shortage of good quality evidence suggests that a crucial strategy to reduce the prevalence of inappropriate care will be at least two-fold, involving substantial expansion of efforts to address these gaps in evidence through more relevant and higher quality clinical research,^{67–69} and closer adherence to best practices for reducing bias due to conflicts of interest.⁷⁰

Closely related to bias due to conflicts of interest, and poor quality research, is the ever-expanding number of, and definitions for, diseases that then require additional research. An urgent need exists for unbiased, evidence-based generation and consensus for creating and modifying disease definitions. No global rules or referees have been identified to oversee the development of new disease and predisease definitions, including the so-called threshold creep of disease classifications.⁷¹ Such a body is required to modulate the rise of overdiagnosis and resultant overtreatment, which might include revisions to treatment recommendations based on risk profile of treatment versus no treatment, and prognosis.

Trends are also shifting internationally with professionals now being explicitly directed to consider the cost of interventions, with a responsibility to reduce waste and improve the value of care. This shift is occurring via many of the financial incentive levers presented throughout this Series paper, but also through efforts such as the Lean method⁷² to improve process efficiency; education at the graduate level;^{3,73} and explicit guidance—eg, from The National Institute for Health and Care Excellence²⁸ and Choosing Wisely.¹⁸

System leaders

System leaders are defined as civil service administrators and those in executive positions at arm's-length government organisations (eg, safety and quality commissions), non-government organisations, and third party payers or insurers. The role for system

leaders in achieving the right care is extensive. In this section, we discuss potential leverage points in the delivery, financial, and governance arrangements within which care is provided.

Foremost at the delivery level is a robust primary care system.⁷⁴ International comparisons of health outcomes in various health-care systems have shown the importance of primary care for driving appropriate care. The provision of ready access to robust high-quality primary care underpins many of the leverage options discussed in this Series paper, from bolstered SDM to integrated care.^{75,76}

All levels of care could benefit from a comprehensive, regionally integrated health information technology (HIT) infrastructure, complete with electronic health records (EHRs), and computerised physician order entry (CPOE) systems. EHRs with CPOE designs can include algorithms, clinical pathway analysis, utilisation and cost information, vetting of orders, and restriction of tests to ensure an appropriate test repertoire. Many HITs and EHRs now have such decision tools, all of which could be used to prompt appropriate high-value care.⁷⁷ To date, individual studies have shown little effect of EHRs for elements of quality improvement,⁷⁸ but knowledge is building of the conditions through which single-component versus multifaceted interventions are more or less effective in changing clinical behaviour.^{79,80} A systematic review⁸¹ identified 19 studies of the impact of CPOE on laboratory testing. The CPOE systems (both with and without decision support) showed an overall trend towards reduced test volume and cost, when compared with no CPOE. Overall, fewer tests, fewer inappropriate tests, and a considerable reduction in the median time to appropriate treatment occurred in the decision support group. These positive results must also be viewed against concerns that first generation EHRs focus excessively on revenue enhancement in some health systems, are too rigid to allow appropriate individualisation of care, and detract from other, equally important aspects of the right care— eg, eye contact and empathic listening. These issues require urgent research to help inform the incorporation of human design factors and the evolution of more intelligent algorithms.

The structuring of financial incentives and payment rules to support the right care is undergoing renewed attention internationally, with explicit endorsements to link payment with some aspects of quality. For example, a 2013 US Institute of Medicine review of cancer care in the USA⁸² called for Medicare and other insurers to recognise and compensate providers that follow the Choosing Wisely recommendations. Many countries are implementing financial incentives for patients (eg, co-payments and conditional cash transfers), as well as rewards or penalties for clinicians, clinics, and hospitals. A set of financial leverage options are listed (the table).

Furthermore, system leaders are exploring initiatives intended to promote rapid adoption of high-value innovations, particularly those that have the potential to

displace existing lower-value interventions. The MaRS EXCITE programme is one example whereby the needs of patients, as well as the evidence requirements of regulators and funders, are prioritised at the development phase, rather than later when a product or service has diffused through a system only to be deemed inadequate on the grounds of safety, effectiveness, or cost-effectiveness and when considerable risks to patients and wasted resources could have already been incurred.^{83,84} This programme sets a vision for nations to fund large patient-relevant clinical trials to balance those dominated by product development cycles of industry,^{85,86} to establish regulatory standards attentive to superiority when patent protections are sought, and where equivalence or non-inferiority triggers downward pricing pressures; and to fund research to investigate services without prospect for short-term profit.

To avoid both overuse and underuse, system leaders must also appraise their systems' investment in such resources as per capita clinical labour and hospital beds. It is widely understood that underuse can occur when availability of resources is inadequate. If a country does not have enough doctors and nurses, citizens' health-care needs will not be adequately addressed. The effect that excess capacity can have on overuse is less well recognised, particularly of services that are delivered at the physician's discretion, such as follow-up visits and treatment in hospital.⁸⁷

Geographical variation in supply-sensitive services poses a problem for all system leaders who would aim to match the capacity of their delivery system to the needs of the population. Many of the methods used to detect a need for increasing per capita supply of resources, such as hospital occupancy rates, and primary care physicians who are able to accept new patients, do not always provide an accurate indication of need for additional beds and personnel. Some efforts to curb excess hospital capacity, such as certificate of need legislation, have had highly variable effects by region, depending upon the political power of existing hospitals to either gain permission to expand or to exclude competitors. Perhaps the best way for system leaders to determine the right capacity to meet local health needs is by looking to systems that have good outcomes using the least resources.^{27,88}

Government policy makers

Mobilising system leaders (eg, bureaucrats) often requires high-level political will and permission, support, or mandate from politicians specifically. This mobilisation is crucial for the scoping of any structural reforms through to their implementation, particularly when broad-based stakeholder commitment, large-scale infrastructure investments, or legislative change is required.⁸⁹

We advocate for systematic priority-setting processes as a core requirement for countries to purchase high-value, appropriate care. HTA, for example, is now firmly engrained worldwide in the health-care resource

For the MaRS EXCITE programme see <http://www.marsdd.com/systems-change/mars-excite/mars-excite/>

Panel 3: Caesarean (c)-section approaches that show promise with regard to reducing overuse of care³²

- In 2012, Italy set regional targets for c-section incidence, which probably helped reverse the trend in c-section incidence in provinces with the highest rates.
- In Spain, some hospitals used a clinical support tool to assess the need for c-sections, which led to a small reduction in use.
- Hospitals in Belgium received feedback on variations in c-section incidence, which led to a convergence in rates among hospitals with both high and low incidence.
- Several countries have introduced financial incentives. France reduced the gap between the prices paid by health insurance for c-sections and normal delivery. Similarly, England decided to align the prices of the two procedures. Korea implemented a pay-for-performance scheme for hospitals, which slightly reduced c-section rates.

C-sections represent a tale of two extremes: a considerable underuse problem in the lower-income and lower-middle-income countries coexisting with overuse. On the one hand, skilled resources and infrastructure might not be available in rural and remote areas in which they are needed to prevent maternal mortality; on the other hand, urban and higher-income contexts face similar overuse issues as high-income countries.

allocation infrastructure (with the notable exception being the USA), but HTA is not a lever per se, but rather a priority-setting feeder for leveraging safe, effective, and cost-effective health care. In many countries, the government must endorse this approach, support its capacity, and follow through on its evidence-based findings.⁹⁰

Although HTA and associated economic evaluation processes have become indispensable, especially regarding the value-based purchasing of pharmaceuticals, these processes have predominantly focused their attention on new and emerging health services and technologies. Little capacity exists for assessing services and technologies that are already established within health systems, but that nevertheless offer no or low-value. This situation has been referred to as being “stuck with the old and overwhelmed by the new”.²⁰ Many countries are realising this shortfall, and expanding the focus of HTA to include reviews of well established services (health technology reassessment [HTRA]).³⁹ Both Canada (Ontario) and Australia, for example, have developed successful HTRA initiatives within their fee-for-service systems.^{91,92} For other countries, the introduction of robust HTA and HTRA processes represent a key step towards encouraging the prevention of underuse and overuse.⁹³ In recognising this potential, particularly for low-income and middle-income countries (LMICs), the Bill & Melinda Gates Foundation has

provided a grant to the International Decision Support Initiative, supporting governments of LMICs and donors in making resource allocation decisions for health care, guiding options for the design, adjustment, and assessment of health benefit plans in the context of UHC.⁹⁴ Some leverage points (table) have considerable potential for implementation to support UHC, as a result of robust HTA and HTRA processes.

An extension of HTA processes would see health systems incorporate public reporting, such as the increasing trend in several countries to publish atlases of variation for the first time.³² Some Organisation for Economic Cooperation and Development countries are becoming quite sophisticated in how information is presented, as seen in England through the National Health Service Atlas, Outcomes benchmarking support packs, and the Commissioning for value data pack.⁹⁵ Italy has been particularly successful with target diagrams so policy makers can make sense of them.³² Systematic reporting for a select number of high-cost, high-volume procedures allows scope to identify outliers, and creates opportunity for discussion with local decision makers and providers (panel 3). Local-level analysis is superior to patient-level data to identify possible unmet needs. Patient data help to contextualise patients who received low-value care³¹ with potential also to identify patients who required treatment but did not receive it.⁵⁹ Another soft touch policy that shows promise is setting regional or local targets; Italy (eg, for select health-care activities) and Belgium (eg, diagnostic imaging) have had success in this area.³² Although multiple policies and approaches are necessary, the relationship between policy type and the effect on regional variations shows mixed success.

Pay-for-performance has been widely used for addressing underuse of high-value services in a wide range of health systems in both high-income countries and LMICs. Although financial incentives are clearly important as drivers of health-care use, the success of pay-for-performance approaches has been mixed, perhaps because of limitations in both the design and implementation of incentives,^{96,97} but just as likely because these approaches are inadequate single-focus solutions to complex problems. Moreover, as a lever for addressing overuse, pay-for-performance is largely untested, but would need to overcome existing financial incentives (eg, fee-for-service), as well as other drivers of overuse. In a somewhat different frame, payers have introduced schemes that withhold payment for services that resulted from a preventable complication or penalise hospitals for high rates of avoidable re-admissions and complications.^{98,99} Controversy has arisen, however, about appropriate accounting for patient risk factors and it is unclear how effective such negative payment incentives will be relative to alternatives.¹⁰⁰

Alongside HTA and HTRA infrastructure support and targeted financial incentives, funding and payment structures govern the general flow of resources through

the health system. A spectrum of approaches exists to fund the delivery of health care from global budgets attached to a specific structure (such as a hospital), whereby payment is completely detached from the delivery of services, to fee-for-service or cost-based reimbursement, in which payment is strictly linked to the number and intensity of services. Many health systems rely on fee-for-service to pay for physician and ancillary services and research has shown that related pricing distortions (specifically, differential profit margins across services) can drive both underuse and overuse. Moreover, even in health systems that rely more heavily on block funding, isolated payment arrangements that prevent the funds from following patients across sites of care can lead to both underuse and overuse. As a result, many countries are looking to create organised networks of providers with financial accountability for quality (including outcomes), patient experience, and the total cost of care.

The US Affordable Care Act introduced the option for Medicare to pay so-called accountable care organisations on the basis of a virtual global budget for all patients who use the primary care services of the system.^{49,50} Some accountable care organisations share both upside and downside risk relative to a spending target for the population, and payments are also affected by performance on a set of quality measures. In England, clinical commissioning groups and other new entities foreshadowed by the 2014 National Health Service 5-year Forward View⁹⁵ adopt a similar role as the nexus of health-care prioritisation at the local level. Similar accountability models can also be designed around a narrower set of services, such as those indicated for the treatment of a condition or related to an acute episode, such as a hip fracture. The Netherlands have introduced episode-based payment for diabetes care, prepaying for a defined set of recommended services to encourage local care groups of general practitioners to reduce costs.¹⁰¹ Furthermore, more than 300 million new insurance beneficiaries in publicly funded health insurance programmes in India are now covered for hospital costs through single, pre-agreed grouped payments, which even include transportation and medicines provided at discharge.¹⁰²

In theory, global payment—at either the population (also known as capitation) or episode level—encourages the accountable provider to consider both the costs and benefits of every service and thus increase the value of care delivered. Indeed, burgeoning research shows that global payment can reduce cost relative to fee-for-service contracts and disproportionately diminishes low-value services.^{49,103} However, whether global payments could also reduce the use of high-value services is unclear.

In European countries, efforts to introduce bundled payment for services closely linked to clinical guidance are showing promise,¹⁰⁴ leading to better protocols and standards of care (Netherlands, Portugal, Sweden). However, episode-based payments could have some downsides relative to population-based global payment

because providers can induce unnecessary episodes of care or push care outside of the funded group, resulting in the appearance of savings at one level, but not from the broader payer's perspective.^{105–07} Incremental changes to systems that rely heavily on fee-for-service are a necessary part of addressing overuse and underuse.¹⁰⁸ Evidence suggests that the level of fees both in absolute and relative terms affects the frequency of use of individual services, suggesting that adjustments to fee-for-service that shift the emphasis from low-value to high-value care is a policy worth pursuing.¹⁰⁹

Furthermore, reducing the fear of litigation through so-called no fault systems provides important opportunities to enable clinical decision making to be about the patient and nothing else.¹¹⁰

Implementation considerations and fit-for-purpose change

As we have noted in paper 3 of this Series,³ key drivers of care operate at the global level. These drivers include trade agreements, international aid, media networks, multinational corporations, and, increasingly, professional societies. Traditional intergovernmental global health organisations have to date played a small role in efforts to improve quality of care delivery. Much work is to be done by international institutions to develop adequate frameworks for promoting the right care around the world, such as establishing international guidelines to ensure high-quality standards for biomedical research, open access to clinical data, and widely accepted codes of conduct for health-care professionals.

The international initiatives discussed within this Series paper are instructive. An analysis of these initiatives highlights numerous shared challenges. Comprehensive and lasting reform requires the following approaches: collective acknowledgment of the concurrent problems of overuse and underuse; the generation of will—political, professional, and social—for broader stakeholder support and the process of carrying reform, with ongoing stakeholder consultation and participation; high-level commitment to ensure that priority setting is part of an explicit, formal, and well resourced policy agenda beyond short-term political timelines; transparent decision making frameworks removed from vested interests; clear objectives and nomenclature, articulating an ethic of waste reduction, and minimising opportunity costs rather than rationing; and the allocation of resources for data collection, monitoring, analysis, and sharing. We must acknowledge that research evidence in this domain is a necessary, but not sufficient ingredient for change. Research waste, bias, and residual uncertainty is simply too prevalent to assume that the evidence alone will steer the course towards the right care.⁶⁹ One key tenet should be that the burden of evidence for safety, effectiveness, and cost-effectiveness rests with the product developer or sponsor, not patients and payers (including tax payers) of health care. An important perspective would hold that entrenched legacy services ought to also be subjected to

the rigorous standards that are increasingly applied to new and emerging technologies and practices. If, after years of use, evidence is not balanced in favour of a practice (and some doubt exists) then a precautionary perspective appears warranted. Restoring the burden of proof is one possibility—placing the inferred expectation for scientifically robust demonstrations of safety, effectiveness, and cost-effectiveness back on the sponsor of a product. Overcoming political, professional, and social resistance to change is a key implementation consideration. However, a shift is undoubtedly occurring in this regard internationally, posing a wonderful opportunity for effective change.

Conclusions

The modern history of health care is littered with policy and practice inaction in the face of inappropriate care, often justified by an absence of evidence or uncertainty about what might result—Machiavelli's "new order of things".¹¹¹ This lack of action should no longer be acceptable. Although the scale of the problem is vast and complex, a range of potentially effective remedies are available, with many more needed. Evidence-based medicine, HTA, shared decision making, and countless other movements have surely nudged health systems to a point whereby we must ultimately acknowledge that a decision not to act is still a decision, and one with implications for people's health. As efforts to improve the delivery of care continue worldwide, we must recognise that if the objective is to improve health, delivery systems need to be properly scaled and adapted to local needs and socioeconomic conditions to be maximally effective. Furthermore, delivery system leaders should remain humble about their systems' contributions to health and should be unburdened from the task of substituting less effective medical spending for social spending. Transitions from the norm invariably cause conflict, but if efforts to achieve the right care are able to capture the full opportunity in front of us, the benefits to the wellbeing of patients, professionals, and the public as a whole are too great to condone inaction.

Contributors

AGE, SB, MBR, PL, JNL, HS, ST, and VS drafted the outline. AGE led the redrafting; first draft construction of panels were led by AGE, JNL, MBR, VS, and SB (panel 2), VS, SB, and AE (panel 1), AE (table first draft), AE, SN, HS, and PL (table second draft), and DS (panel 3), with subsequent input from all authors on all panels. All authors led a section of the manuscript and cross-contributed to sections and examples throughout the paper, provided substantial revisions, and approved the final version of the manuscript.

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