The health care system in the United States is undergoing seismic shifts in insurance coverage, payment mechanisms, and modes of delivery—all at once. In 2014 alone, an estimated 15 million uninsured Americans will receive health coverage between the Medicaid expansion and the health insurance marketplaces engendered by the Affordable Care Act (ACA). Both government and private payors are driving a transformation from volume-based reimbursement to value-based purchasing through bundled payments, global budget contracts, accountable care organizations, and other new payment models. And perhaps most importantly, the actual structures of the health care delivery system are changing. While hospitals remain important centers of gravity in the health system, services are increasingly being delivered via ambulatory care. The shift to ambulatory care is giving rise to new delivery structures, such as retail clinics and urgent care centers, as well as a reinvention of existing ambulatory care capacity, as seen with the patient-centered medical home model and the movement toward team-based care. To protect the interests of the public, oversight of ambulatory care services must keep pace with these rapid changes.

1 | Provenance

In January 2012, Governor Andrew Cuomo and Commissioner of Health Nirav Shah charged the PHHPC with the development of a health planning framework that drives health system improvement. The December 2012 report of the Public Health and Health Planning Council (PHHPC)—entitled *Redesigning Certificate of Need and Health Planning*—examined trends in health care organization and sought to align Certificate of Need (CON) and health planning processes with these changes. The PHHPC recommended that deliberations on health planning be conducted through regional, multi-stakeholder collaboratives. By recommending to retain licensure requirements but eliminate need assessments for primary care facilities, it anticipated the expansion of capacity needed for the one million New Yorkers who will gain coverage under the ACA. Additional recommendations dealt with regulatory oversight of physician practices; modifications to the process of establishing new health care facility and home care agency operators; strengthening health system governance review; supporting expanded access to hospice; and incorporating quality and population health factors into CON review. The December 2012 PHHPC report laid the groundwork for strategic alignment of regulatory oversight with new models of health care organization and payment.

In this report, the PHHPC builds out the framework for public oversight of ambulatory care services. Three introductory principles are germane. First, the vision of high-performing ambulatory care remains rooted in the Triple Aim (better health, higher-quality care, lower costs)—with a particular emphasis on *continuity of care* for patients. Second, there is a need to better define the taxonomy of ambulatory care services. From the perspective of the state government, clarification requires improved reporting from new health care entities (e.g., retail clinics); connections with regional and state health information technology hubs; and coordination among state agencies including the Department of Health, the Department of Mental Hygiene, the Department of Financial Services, and the new Health Plan Marketplace. A uniform nomenclature would also facilitate the consumer's understanding of rights and responsibilities. Third, the regulatory mechanisms employed—from mandatory reporting to licensure to regional planning to Certificate of Need—should remain flexible and match the degree of consensus regarding the appropriate regulatory path. For areas with considerable uncertainty about the consequences of any new regulation, incremental steps—often beginning with reporting requirements—can help shed light on a prudent way forward.

2 | A Vision for Ambulatory Care

The landscape of health care delivery is undergoing rapid metamorphosis. In the future, more care will be delivered in the outpatient setting; it will be managed by teams of providers, often working across distributed networks; and much of it will be virtualized. Existing institutions are restructuring around this reality, as evinced both by the evolution of certain hospitals into full health care delivery systems and by the emergence of large multispecialty physician groups—with some of each taking on financial risk. Risk-based contracts have shown promise in slowing the increase in medical expenditures for public payors (e.g., Medicare) as well as private payors (e.g., UnitedHealth Group).[1,2] Many of the arrangements are grounded in the concept of "accountable care," in which a group of providers accepts responsibility for all health care services required by a given population—and is held accountable for cost and quality outcomes. Of the 148 Medicare Accountable Care Organizations (ACOs) currently operating nationwide, 15 are located in New York. Two-thirds of the 15 are sponsored by physician groups rather than hospitals.[3] Meanwhile, other categories of "disruptive innovators"—such as retail clinics, startup primary care networks, and ambulatory surgery centers—are testing out models of care with the potential to upend current payment and delivery paradigms. In this environment, the primacy of acute care as the financial driver of the health care system is challenged and the role of ambulatory care is heightened.

2.1 The Triple Aim

Amidst this turmoil, the principles undergirding the Affordable Care Act and the Medicaid Redesign Team's initiatives—the Triple Aim—remain a useful polestar. The core tenets of the Triple Aim[4] are both a yardstick for what has been accomplished and a set of aspirations for the future:

- *Population health*: Ambulatory care should help shift the locus of health care from facilities to communities, with a concomitant refocusing on long, healthy lives for all (operationalized as health-adjusted life expectancy) as the metric of interest. This approach adopts a comprehensive notion of health determinants that are spread across domains of behavioral risk, social and economic circumstances, environmental exposures, and medical care.[5] The balance and effects of many of these determinants, e.g., availability of healthy foods, parks and other safe places to play and exercise, exposure to environmental irritants, and safe housing, are specific to geographic locale. Several key provisions of the ACA highlight population health, such as Internal Revenue Service requirements for tax-exempt hospitals to demonstrate meaningful efforts to improve the health of the communities they serve.[6] In New York, the State Prevention Agenda (also known as the State Health Improvement Plan) includes evidence-based practices for improving population health in each of five priority areas and provides guidance for local stakeholders in their efforts to assess and improve community health and reduce health disparities. New York State generally ranks in the second quartile on measures of healthy living collated by the Commonwealth Fund and the United

[1] Centers for Medicare & Medicaid Services. "Pioneer Accountable Care Organizations succeed in improving care, lowering coss," July 16, 2013. Available online at: http://go.cms.gov/18ABrMG.
[2] UnitedHealth Group Inc. "UnitedHealthcare Expects to More than Double Industry-Leading Accountable Care Contracts to $50 Billion by 2017," July 10, 2013. Available online at: http://bit.ly/1eQHZNv.
[3] Burke, Gregory. "Trends and Changes in the New York State Health Care System: Implications for the Certificate of Need (CON) Process. United Hospital Fund, 2012.
[4] Berwick, Donald M., Thomas W. Nolan, and John Whittington. "The Triple Aim: Care, Health, and Cost." *Health Affairs* 27.3 (2008): 759-769.
[5] Institute of Medicine. *Primary Care and Public Health: Exploring Integration to Improve Population Health.* Washington, DC: National Academies Press; 2012.
[6] Young, Gary J., Chia-Hung Chou, Jeffrey Alexander, Shoou-Yih Daniel Lee, and Eli Raver. "Provision of Community Benefits by Tax-Exempt U.S. Hospitals." *New England Journal of Medicine* 368 (2013): 1519-1527.

Health Foundation.[7,8] Improving performance in population health will require the full participation of ambulatory care providers in the State Prevention Agenda.

- *Health care quality*: New York has made strides in improving the quality of health care. For example, in the Medicaid program, National Committee for Quality Assurance (NCQA) commended the state's performance in increasing rates of childhood immunization, controlling blood pressure as part of diabetes management, screening for colorectal cancer, and assisting with smoking cessation.[9] New York's pending 1115 Medicaid waiver could help advance further progress. Yet the world of health care quality improvement has yet to fully embrace ambulatory care into its purview. The majority of outpatient quality measures focus on preventive care, chronic disease care, and patient experience—important domains, but exclusive of equally important measures such as diagnostic accuracy, appropriateness of testing, and rates of medication errors.[10] Therefore, efforts to improve ambulatory care must optimize quality metrics as well as refine the methods of measurement.

- *Costs of care*: New York has traditionally performed poorly on evaluations of health care efficiency, scoring 50th among all states on avoidable hospital use and costs in the 2009 Commonwealth Fund state scorecard.[11] Again, Medicaid has been a bright spot, with reforms proposed by the Medicaid Redesign Team generating almost $5 billion in savings thus far. Still more can be done, particularly with the Medicare and commercially-insured populations. A recent Institute of Medicine study of geographic variation in U.S. health care spending identified two major cost drivers, both of which carry implications for organization of ambulatory care. In the Medicare population, most of the variation in spending per beneficiary was in post-acute care (services provided by skilled nursing facilities, rehabilitation and long-term care hospitals, home health agencies, and hospices).[12] In the commercially-insured population, post-acute care is only a minor contributor to variation in spending. Instead, price variation is the predominant factor, accounting for about 70% of the total expenditure variation.[13] In both cases, post-acute care variation and price variation, careful regulation to help shape the ambulatory care market has the potential to generate greater efficiency in the broader health care system. Per capita spending, with a particular focus on high-cost individuals, must remain a fundamental metric of interest in the Triple Aim.

One additional principle is as significant as the Triple Aim when considering ambulatory services: continuity of care. Continuity of care is a "Triple Aim home run"—it helps bring about better health, improved health care quality, and lower costs.[14] While some patients, particularly younger patients with acute illnesses, may prefer access to continuity, many more place high value on continuity of care, particularly those who are older or have multiple chronic conditions. A growing corpus of evidence demonstrates the systemic effects of continuity of care: for example, a study of over 3 million Medicare beneficiaries showed an inverse effect between primary care continuity and preventable

[7] McCarthy, Douglas, S. K. H. How, C. Schoen, J. C. Cantor, D. Belloff. "Aiming Higher: Results from a State Scorecard on Health System Performance." The Commonwealth Fund, October 2009.
[8] America's Health Rankings. United Health Foundation, 2012. Available online at: http://www.americashealthrankings.org/Senior/NY.
[9] National Committee for Quality Assurance. "State of Health Care Quality—New York." March 28, 2013. Available online at: http://bit.ly/199GF01.
[10] Bishop, Tara. "Pushing the Outpatient Quality Envelope." *Journal of the American Medical Association* 309.13 (2013): 1353-1354.
[11] McCarthy, Douglas, S. K. H. How, C. Schoen, J. C. Cantor, D. Belloff. "Aiming Higher: Results from a State Scorecard on Health System Performance." The Commonwealth Fund, October 2009.
[12] Institute of Medicine. "Interim report of the committee on geographic variation in health care spending and promotion of high value care: preliminary committee observations." 2013. Available online at: http://books.nap.edu/openbook.php?record_id=18308.
[13] Newhouse, Joseph P. and Alan M. Garber. "Geographic Variation in Health Care Spending in the United States." *Journal of the American Medical Association* 310.12: 1227-1228.
[14] Gupta, Reena and Thomas Bodenheimer. "How Primary Care Practices Can Improve Continuity of Care." *JAMA Internal Medicine* 2013 Sep 16 (e-Publication ahead of print).

hospitalizations.[15] To the extent new models of ambulatory care disrupt continuity of care, they may have negative ramifications for cost, quality, and health. The first step in tracking this phenomenon may be for primary care practices to begin measuring their patients' continuity of care.

2.2 A foundation of high-performing primary care

High-quality ambulatory care depends on the bedrock of excellent primary care. New York must both improve and extend primary care to accommodate the million New Yorkers will gain coverage via the Affordable Care Act. Because new models of ambulatory care may blur the boundaries of primary care, it is useful to invoke the Institute of Medicine's definition of primary care: "The provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of health care needs, developing a sustained partnership with patients, and practicing in the context of family and community."[16] While superlative models of primary care will be context-dependent across diverse communities, a few *sine qua non* elements are becoming apparent:

- *Patient-centered medical home model with team-based care delivery.* The Joint Principles of the Patient-Centered Medical Home, adopted in 2007 by the American Academy of Pediatrics, the American College of Physicians, the American Academy of Family Physicians, the American Osteopathic Association, and subsequently endorsed by dozens of specialty societies, describe the importance of each patient having "an ongoing relationship with a personal physician trained to provide first contact, continuous and comprehensive care…[T]he personal physician leads a team of individuals at the practice level who collectively take responsibility for the ongoing care of patients."[17] The American College of Physicians (ACP) recently endeavored to further define team-based care in a position paper, stating "A clinical care team for a given patient consists of the health professionals—physicians, advanced practice registered nurses, other registered nurses, physician assistants, clinical pharmacists, and other health care professionals—with the training and skills needed to provide high-quality, coordinated care specific to the patient's clinical needs and circumstances."[18] Importantly, the ACP position paper advocates for a cooperative interprofessional approach as a necessary coping strategy for looming physician shortages.

- *Population health management with sophisticated risk stratification.* Taking responsibility for population health in primary care requires managing the health outcomes of a group of individuals, often organized into patient panels. This perspective centers around deploying evidence-based interventions and disease management categories so as to triage and allocate health care resources in a cost-effective manner. The U.S. Department of Veterans Affairs, for example, has operationalized the concept by risk-stratifying populations of patients and customizing interventions to specific risks. Based on longitudinal EHR data spanning up to two decades, a Care Assessment Need (CAN) score, a statistical model, predicts a patient's risk of hospitalization or death at 90 days or 1 year with high reliability and validity.[19] The CAN score therefore stratifies patients who are at greatest risk for adverse outcomes; enhanced care management services can then be directed to those veterans.

[15] Nyweide, David J., Denise L. Anthony, Julie P.W. Bynum, et al. "Continuity of Care and the Risk of Preventable Hospitalization in Older Adults." *JAMA Internal Medicine* 2013 Sep 16 (e-Publication ahead of print).
[16] Donaldson M, K Yordy, N Vanselow, eds. "Defining Primary Care: An Interim Report." Washington, DC: National Academies Press, 1994.
[17] American Academy of Family Physicians, American Academy of Pediatrics, American College of Physicians, American Osteopathic Association. Joint Principles of the Patient-Centered Medical Home. Available online at: http://bit.ly/1haRVhL. 2007.
[18] Doherty, Robert B. and Crowley, Ryan A. "Principles Supporting Dynamic Clinical Care Teams: An American College of Physicians Position Paper." *Annals of Internal Medicine* 2013 Sep 17 (e-Publication ahead of print).
[19] Wang L, B Porter, C Maynard, et al. "Predicting Risk of Hospitalization or Death Among Patients Receiving Primary Care in the Veterans Health Administration." *Medical Care* 51 (2013): 368-373.

- *High-risk patient management.* As popularized by Atul Gawande's *New Yorker* article, "The Hot Spotters," addressing the needs of the sickest and most vulnerable patients can be another Triple Aim home run. Nationally, just 10 percent of the population is estimated to account for about 64 percent of health care expenditures, often because of overutilization of the hospital, emergency room, and other acute care resources.[20] By addressing care coordination, targeting intensive interventions, and ensuring greater access, this segment of the population benefits from improved health while reducing costs. Many primary care practices are now testing high-risk patient management, whether in an "ambulatory intensive care unit" or under another designation. Preliminary evidence from programs for high-risk elderly patients shows modest reductions in hospital and emergency department utilization—although it is unclear how generalizable these findings are to a broader (non-elderly) high-risk population.[21]

- *Rapid but judicious access to specialty expertise.* The market for specialty services appears dissimilar from different vantage points. For private providers who take care of affluent, generally commercially-insured patients, the problem may be supply-driven overuse of expensive specialty resources. Meanwhile, patients and providers in safety-net systems often face a tremendous mismatch between supply and demand for specialty services—leading to significant wait times and delays in care. Innovations in accessing specialty expertise may help with both sides of the issue, by improving the value of specialty care while distributing its reach. For instance, in San Francisco, a program known as eReferral—piloted in a safety-net system—uses simple technology to allow for expeditious, iterative communication between primary care providers and specialists, sometimes obviating the need for in-person consultation.[22] In the same vein, a national program known as Project ECHO has shown that with the right staffing and technology infrastructure, primary care providers can co-manage patients with complex, chronic disease like Hepatitis C.[23]

- *Integrated behavioral health.* Individuals with serious physical health problems often have concomitant mental health issues, and nearly half of those with any mental disorder meet the criteria for two or more disorders.[24] New York has been a leader in beginning to incorporate behavioral health services into primary care, particularly through Medicaid Health Homes. More broadly, however, most primary care doctors are ill-equipped or lack the time to fully address the psychosocial issues underlying many patients' visits. In some cases, there is no ready access to dedicated behavioral health professionals—and rarely are physical health and behavioral health providers co-located to enable "warm handoffs" between the two. A number of models for integrated or collaborative behavioral health and primary care are emerging.[25] In one example, the Southcentral Foundation's Nuka System of Care in Alaska, behavioral health is normalized as a routine component of medical care, with integrated charts, care teams, and clinic design facilitating a spectrum of collaboration, from informal consultation to joint visits to more formal referrals.[26]

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[20] Cohen, S and W Yu. "The Concentration and Persistence in the Level of Health Expenditures over Time: Estimates for the U.S. Population, 2008-2009. Statistical Brief #354." Agency for Healthcare Research and Quality, 2012.
[21] Peterson, Kim, Mark Helfand, Linda Humphrey, et al. "Effectiveness of Intensive Primary Care Programs: Evidence Brief." Evidence-based Synthesis Program, Portland VA Medical Center. November 28, 2012.
[22] Chen, Alice H., Elizabeth J. Murphy, and Hal F. Yee, Jr. "eReferral—A New Model for Integrated Care." *New England Journal of Medicine* 368 (2013): 2450-2453.
[23] Arora S, K Thornton, G Murata, et al. "Outcomes of Treatment for Hepatitis C Virus Infection by Primary Care Providers." *New England Journal of Medicine* 364 (2011): 2199-2207.
[24] Kessler, R., W. Chiu, O. Demler, and E. Walters. "Prevalence, Severity, and Comorbidity of Twelve-Month DSM-IV Disorders in the National Comorbidity Survey Replication." *Archives of General Psychiatry* 62.6(2005): 617-627.
[25] Collins C., D.L. Hewson, R. Munger, and T. Wade. "Evolving Models of Behavioral Health Integration in Primary Care." Milbank Memorial Fund, 2010. Available online at: http://www.milbank.org/uploads/documents/10430EvolvingCare/EvolvingCare.pdf
[26] Driscoll DL, V Hiratsuka, JM Johnston, et al. Process and outcomes of patient-centered medical care with Alaska Native People at Southcentral Foundation. *Annals of Family Medicine* 2013.11(Suppl_1): S41-S49.

Taken together, these components of high-performing primary care provide a foundation for delivering on the Triple Aim and enshrining continuity of care as a central goal of the larger ambulatory care enterprise.

2.3 Innovations in convenient ambulatory care

Across the United States, patients visit health care providers about 50 million times annually for low-acuity conditions such as sinusitis and urinary tract infections.[27] Some of these visits take place in emergency departments, though it is sometimes difficult to discern between low-acuity and urgent conditions *a priori*—and such visits often reflect poor access to primary care rather than poor judgment on the part of patients.[28,29] Indeed, many more than 50 million annual visits might be logged were there shorter wait times for primary care appointments. But the Affordable Care Act's coverage expansion will likely exacerbate appointment delays rather than improve them. Partly in response to such demand, new ambulatory options such as retail clinics (e.g., CVS Caremark's MinuteClinic) and urgent care centers have expanded rapidly in recent years. For example, retail clinic visits increased nationally four-fold between 2007 and 2009 and were estimated to account for almost 6 million annual visits by 2012.[30] Meanwhile, in rural areas, concerns about insufficient emergency care capacity has led to the promulgation of upgraded diagnostic and treatment centers (with limited emergency care capabilities) and the establishment of freestanding emergency departments.

The benefits of these convenient ambulatory care options remain conjectural, although the increased access and low-overhead cost structure seem intuitively the case. On the other hand, risks include decreasing continuity of care and increasing fragmentation. While care provided may be less expensive on a per-visit basis, convenient access may lead to more patients seeking care, increasing overall utilization and spending. Access may be heavily weighted toward more affluent patients depending on payment sources accepted: for example, only about 60% of retail clinics around the country accept Medicaid—and usually only a limited form.[31] And reallocation of private revenue to convenient care options could threaten the viability of much needed primary care practices and hospital-based emergency departments.[32]

2.4 Innovations in specialty ambulatory care services

New models of ambulatory care delivering specialty services have complicated relationships between hospitals and physicians over the past two decades. Enhanced physician practices (so-called physician "mega-groups"), non-hospital surgery (including ambulatory surgery centers and office-based surgery), advanced diagnostic imaging centers, and radiation therapy all fall into this category. The number of these facilities has steadily increased—in New York and around the country—as physicians, taking advantage of new forms of technology and available capital, pursue new ventures separate from hospital centers.[33] Proponents argue that such novel arrangements create "centers of excellence" for specialty

[27] Mehrotra A, MC Wang, JR Lave, JL Adams, EA McGlynn. "Retail clinics, primary care physicians, and emergency departments." *Health Affairs* 27.5(2008): 1272-1282.
[28] Adams, James G. "Emergency Department Overuse: Perceptions and Solutions." *Journal of the American Medical Association* 309.11(2013): 1173-1174.
[29] Kellermann, Arthur L. and Robin M. Weinick. "Emergency Departments, Medicaid Costs, and Access to Primary Care—Understanding the Link." *New England Journal of Medicine* 366(2012): 2141-2143.
[30] Mehrotra, Ateev and JR Lave. "Visits to retail clinics grew fourfold from 2007 to 2009, although their share of overall outpatient visits remains low." *Health Affairs* 31.9(2012): 2123-2129.
[31] Mehrotra, Ateev, John L. Adams, Katrina Armstrong, et al. "Health Care on Aisle 7: The Growing Phenomenon of Retail Clinics." RAND Research Brief RB-9491, 2010. Available online at: http://www.rand.org/pubs/research_briefs/RB9491-1.html.
[32] Mehrotra, Ateev. "The Convenience Revolution for Treatment of Low-Acuity Conditions." *Journal of the American Medical Association* 310.1(2013) 35-36.
[33] Iglehart, John K. "The Emergence of Physician-Owned Specialty Hospitals." *New England Journal of Medicine* 352(2005): 78-84.

care and, in the case of enhanced physician practices, promote community-based population health. Detractors argue that despite providing complex and costly services, the enhanced arrangements operate with insufficient oversight of safety and quality—and that they cherry-pick more affluent patients.

The amalgamation of "specialty ambulatory care services" multiplies the complexity of each category of service. Enhanced physician practices are in some ways the most natural accountable care organizations—but they can also destabilize existing safety net providers by drawing away commercially-insured patients. Non-hospital surgery spans care sites with drastically different cost structures and regulatory responsibilities. Scant evidence exists to guide patients to appropriate sites of care—and thus the same procedure may be performed in office-based surgery, ambulatory surgery centers, and hospitals. Advanced diagnostic imaging is almost certainly overused, although the underlying reasons are more complicated than financial inducements; defensive medicine, patient preference, and time constraints all likely play a role.[34] Meanwhile, radiation therapy might be appropriately utilized as a whole—but the predilection toward costlier modalities of radiation therapy may warrant scrutiny.

3 | Way Forward

Despite the broad penetrance of convenient care options and specialty ambulatory services across the United States, there are few precedents to call upon with respect to comprehensive ambulatory care oversight. Massachusetts recently chartered a state-level Health Planning Council charged with identifying health care service needs; laying out priorities for addressing those needs; and making recommendations for the appropriate supply and distribution of services. In its first phase, the Council is addressing six areas: behavioral and mental health services; primary care resources; post-acute care; ambulatory surgery; percutaneous coronary intervention; and trauma.[35] Few other states have embarked upon a wide-ranging assessment of regulation of ambulatory care services. New York therefore has an opportunity to be a trailblazer in developing sound oversight while encouraging innovation in the field. The work of the Medicaid Redesign Team on Health Homes—and the primary care expansion and new care models in the state's proposed 1115 Medicaid waiver—demonstrate New York's commitment to ambulatory care. This report's work builds on those antecedents and the PHHPC's redesign of Certificate of Need to pave a path forward.

The report's recommendations regarding oversight of ambulatory care flow from five specific premises:

- Regulation should strive to create conditions for fair competition in the ambulatory care market, particularly between institutional providers and independent professional practices. However, in cases of market failure, particularly in underserved areas, other regulatory considerations may predominate in order to develop highly integrated "utility-style" models of care.
- The public's awareness of novel ambulatory care services is a paramount consideration. Standard nomenclature for services and public signage should serve to reduce consumer confusion.
- Patient safety and quality standards for new models of care should equal or exceed existing clinical standards.
- Continuity of care, particularly with patients' primary care practices, should be preserved and promoted.
- A robust data infrastructure, implemented via interoperable health information technology systems, should support providers' reporting requirements as well as patients' continuity of care. Over time, the availability of this data should enable further refinement of the state's own regulatory system.

[34] Smith-Bindman R., DL Miglioretti, E Johnson et al. "Use of diagnostic imaging studies and associated radiation exposure for patients enrolled in large integrated health care systems, 1996-2010." *Journal of the American Medical Association* 307.22(2012): 2400-2409.
[35] Biondolillo, Madeleine. "Informational Briefing on the State Health Plan." Health Planning Advisory Committee, Massachusetts, July 19, 2013. Available online at: http://1.usa.gov/1983iYA.