

Adoption of Cardiovascular Risk Reduction Guidelines: A Cluster-Randomized Trial



WHAT'S KNOWN ON THIS SUBJECT: Cardiovascular risk begins in childhood. New clinical guidelines established a care strategy for lowering risks. Incorporation of guidelines into routine practice lags due to barriers related to knowledge and attitudes about guidelines, as well as behaviors of practitioners, patients, and clinical systems.



WHAT THIS STUDY ADDS: This study demonstrated that a multifaceted approach including tools, education, and support for changes in practice systems can accelerate the adoption of guidelines during routine pediatric well-child visits, compared with dissemination of the guidelines alone.

abstract



BACKGROUND AND OBJECTIVES: Cardiovascular disease (CVD) and underlying atherosclerosis begin in childhood and are related to CVD risk factors. This study evaluates tools and strategies to enhance adoption of new CVD risk reduction guidelines for children.

METHODS: Thirty-two practices, recruited and supported by 2 primary care research networks, were cluster randomized to a multifaceted controlled intervention. Practices were compared with guideline-based individual and composite measures for BMI, blood pressure (BP), and tobacco. Composite measures were constructed by summing the numerators and denominators of individual measures. Preintervention and postintervention measures were assessed by medical record review of children ages 3 to 11 years. Changes in measures (pre–post and intervention versus control) were compared.

RESULTS: The intervention group BP composite improved by 29.5%, increasing from 49.7% to 79.2%, compared with the control group (49.5% to 49.6%; $P < .001$). Intervention group BP interpretation improved by 61.1% (from 0.2% to 61.3%), compared with the control group (0.4% to 0.6%; $P < .001$). The assessment of tobacco exposure or use for 5- to 11-year-olds in the intervention group improved by 30.3% (from 3.4% to 49.1%) versus the control group (0.6% to 21.4%) ($P = .042$). No significant change was seen in the BMI or tobacco composites measures. The overall composite of 9 measures improved by 13.4% (from 48.2% to 69.8%) for the intervention group versus the control group (47.4% to 55.2%) ($P = .01$).

CONCLUSIONS: Significant improvement was demonstrated in the overall composite measure, the composite measure of BP, and tobacco assessment and advice for children aged 5 to 11 years. *Pediatrics* 2014;134:e732–e738

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KEY WORDS

cardiovascular disorders, children, cluster randomized trial, guideline implementation, prevention, quality improvement

ABBREVIATIONS

BP—blood pressure
CVD—cardiovascular disease
E-CARE—East Carolina University Network
EMR—electronic medical record
MOC—maintenance of certification
QI—quality improvement

Dr LaBresh conceptualized and designed the study, coordinated study activities, supervised data analysis, supervised development of study tools, and drafted portions of the initial manuscript; Drs Ariza and Lazorick participated in study design, coordinated activities and data collection in one of the practice networks, drafted portions of the initial manuscript, and critically reviewed manuscript revisions; Dr Furberg led the development of tools and critically reviewed manuscript revisions; Dr Whetstone and Ms Salinas coordinated and conducted data collection in one of the practice networks and critically reviewed manuscript revisions; Ms Hobbs coordinated study activities and critically reviewed manuscript revisions; Ms de Jesus participated in designing the study and critically reviewed the manuscript; Dr Bender conducted the analysis, contributed to, and reviewed portions of the original manuscript; and Dr. Binns participated in study design, supervised participation of one of the practice networks, drafted portions of the initial manuscript, and critically reviewed manuscript revisions. All authors approved the final manuscript as submitted.

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Because health habits are formed very early in life,^{1,2} focusing efforts on promoting healthy behaviors has the potential to prevent risk of chronic diseases known to emerge in childhood.^{2,3} Preventive efforts must occur at a young age given that established unhealthy habits (and their effects) may be resistant to change. Cardiovascular risks develop early, producing atherosclerotic changes in adolescence and early adulthood.^{4,5} Evidence shows that it is likely that children who are obese by 4 to 6 years of age will be obese adults.^{6–8} Elevated blood pressure (BP) in childhood has been associated with decreased learning in children and risk for heart/kidney damage in young adults.^{9–14} Children whose parents smoke are 4 times as likely to initiate tobacco use.¹⁵ Nearly all habitual smokers have initiated tobacco use by 18 years of age.¹⁶ Preventive care visits provide opportunities to identify and address health risks and promote healthy behaviors.¹⁷ In 2011, the National Heart, Lung, and Blood Institute supported the development and publication of the report of the Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents.¹⁸ Although guidelines are useful for setting quality improvement (QI) goals, the adoption of these guidelines may lag up to 5 years after publication.¹⁹ Education alone is not enough to establish meaningful changes in the quality of care.^{20–22} Provider adoption of guidelines occurs more often when practice systems of care undergo change as part of a multifaceted intervention.^{23–25}

We designed the present cluster randomized controlled trial to test the impact of strategies and a set of tools²⁶ for accelerating the adoption of these pediatric cardiovascular risk reduction guidelines by medical practices providing primary care to children. The objective of this study was to determine the extent that

the Young Hearts, Strong Starts QI intervention increased the adoption of select components of the recently published guideline recommendations to reduce cardiovascular disease (CVD) risk in children ages 3 to 11 years. We focused on 3 areas of care: BMI documentation and interpretation with provision of guideline-compliant care for overweight and obese children; BP documentation and interpretation and provision of guideline-compliant care for children with identified elevated BP; and documentation of tobacco-related assessments and counseling.

METHODS

Subjects

The design and rationale of this trial have been reported previously.²⁶ In brief, 32 practices providing care for children ages 3 to 11 years were cluster randomized to intervention and standard dissemination control groups. Participating practices were affiliated with 1 of 2 practice-based research networks: the Pediatric Practice Research Group in the Chicago metropolitan area or the East Carolina University Network (E-CARE), with practices located throughout eastern North Carolina. Each network recruited 16 practices from a pool of 53 practices. Nineteen practices declined participation, and 2 practices were not eligible due to low patient volume. Eight practices in each network were randomized to intervention and 8 to control groups; all practices completed the trial and follow-up data collection. To enhance similarity between groups, practices were cluster randomized based on pairs according to practice size (≥ 5 vs < 5 clinicians), practice location (urban versus not urban), and practice type (pediatric versus family medicine). Patients were sampled for chart review by selecting every third age-eligible child from a list of consecutive well-child visits from the administrative database of each practice, working back from the date of

review. Based on the power calculation described previously, 30 patients were selected for each practice at baseline and 40 patients were selected for the postintervention sample to provide greater statistical power for a multivariable analysis of the results.²⁶ The study was approved by the institutional review boards of RTI International and the sponsoring institutions of the 2 networks, the Ann & Robert H. Lurie Children's Hospital of Chicago and East Carolina University. The institutional review boards did not require written informed consent from physicians or patients/families. No changes in methods were made during the course of the trial. The sample size determination and allocation strategy and assignment were described in detail in the previous methods article.²⁶ Practices were recruited between July and October 2011. Baseline chart abstraction was performed in November 2011 through January 2012 from patient visits that occurred from October 2011 through December 2011. Follow-up chart abstractions were performed in October 2012 through early December 2012 for patient visits between October 2012 and December 2012.

Study Processes and Intervention Strategies

A report of baseline performance with study measures was distributed to intervention and control practices before the start of the intervention. Reports were sent to control practices electronically; at intervention practices, feedback reports were accompanied by an in-person educational session (academic detailing)²⁷ to review the new guidelines.

Intervention

All clinicians at intervention practices had access to an electronic listserv to post questions and describe tests of changes in care delivery, and monthly webinars for QI training, best practice

sharing, and expert topic-based presentations. Clinicians received comprehensive family-directed workbooks on CVD risk reduction behavior change for children for distribution to families. An electronic decision support tool for use on smartphones or tablets was available for interpretation of BMI and BP via a calculator within the tool and a more comprehensive decision support algorithm to provide guideline-based, patient-customized recommendations for BMI, BP, and tobacco.²⁶

Intervention practice physicians were offered participation in an American Board of Pediatrics–approved maintenance of certification (MOC) Part 4 program. Twenty-four physicians at 11 of the 16 intervention practices completed the MOC processes, including attending at least 4 monthly webinars and self-abstracting 10 charts monthly. Study measures selected were BMI documentation; BMI interpretation and management of obese and overweight children; BP documentation, interpretation, and management; and tobacco use, exposures, and preventive counseling. Composites of the measures for each of the 3 areas and an overall study composite were also constructed. Each composite represented the number of opportunities for the practice to adhere to guideline recommendations in each area, calculated as the sum of the numerators divided by the sum of the denominators; these values were calculated for each practice and then aggregated to form the intervention and control composite measures.^{26,28} No changes were made to the study measures during the trial.

Analysis

Data were gathered according to medical record review before and after the intervention period. The data collection strategy and data elements have been previously reported. In brief, medical records were selected from a list of well-

child visits of children aged 3 to 11 years.²⁶ Every third record was selected starting with the most recent until 30 eligible records have been identified. A study staff member from each of the 2 primary care research networks conducted the record abstraction for their participating practices before randomization and at the end of the intervention when practice assignment was known to the practices and study staff. Data abstracted included patient demographic characteristics; measures of height, weight, BMI, and BP; documentation of interpretation of both BMI and BP; and compliance with guideline-recommended interventions based on BMI and BP percentile groups. Chart abstraction questions about whether care met guideline recommendations were adjudicated by a single, experienced pediatrician at each of the 2 networks. For the tobacco measures, second-hand smoke exposure and child use (depending on age), and preventive counseling documentation were assessed. Rates of performance for each measure and composite measure at baseline and at follow-up were determined for the intervention and control practices. Differences (follow-up – baseline) were computed for both the control and intervention practices; between-group differences were examined. Differences in percent change were computed by using generalized estimated equation methods to account for practice-related clustering.²⁶

The impact of patient and practice characteristics was assessed for individual outcome measures but not the composites by using a generalized linear model. Covariates including treatment group, patient gender and age, practice characteristics (size ≥ 5 vs < 5 clinicians) and use of electronic medical records (EMRs), and practice-based research network were analyzed. All covariates (except age) were binary and were treated as categorical covariates in the model. Age was modeled as a continuous linear covariate. These

analyses were conducted with SAS software (SAS Institute, Inc, Cary, North Carolina) using the GENMOD procedure. One outcome measure (BP management recommendations) was not evaluated because of limited available data.

RESULTS

Practices and Patient Characteristics

Characteristics of participating practices were similar (Table 1). Patient subjects were similar between groups based on gender and BMI percentile group (< 85 th BMI percentile vs ≥ 85 th BMI percentile). The mean age of patients was greater in the control group compared with the intervention group (6.3 vs 6.1 years; $P < .001$). Thirty of the practices were pediatric; E-CARE contributed 1 family medicine practice and 1 multispecialty practice. EMRs were in place at study start in 12 practices, and 4 practices implemented EMRs during the intervention period. All enrolled practices completed the entire trial.

Baseline Performance Measures

Both control and intervention practices demonstrated relatively high performance in baseline BMI measurement and interpretation. Medical record documentation of guideline-compliant care for overweight and obese patients was similar between intervention practices and control practices for the composite measure for BMI (Table 2).

Baseline composite and individual measures for BP were similar between groups. High rates of BP were measured and recorded at both control and intervention practices, whereas BP was rarely interpreted.

At baseline, the composite tobacco measure was similar for both control (5.6%) and intervention (4.5%) practice groups; tobacco-related assessment and counseling were uniformly low ($\leq 17.1\%$) for both (Table 2).

TABLE 1 Characteristics of Practices and Patients

Characteristic	Control	Intervention
No. of practices	16	16
No. of clinicians		
≤5	8	9
>5	8	7
Location		
Urban	11	11
Not urban	5	5
Medical record status at baseline and follow-up		
Paper, paper	9	7
EMR, EMR	5	7
Paper, EMR	2	2
No. of patients	1121	1122
Age, mean ± SD, y	6.3 ± 2.7	6.1 ± 2.5
Gender, n (%)		
Male	553 (49.3)	575 (51.3)
Female	564 (50.3)	546 (48.7)
Not documented	4 (0.4)	1 (0.1)
BMI		
≥85th BMI percentile	127 (13.4)	137 (14.3)
<85th BMI percentile	984 (86.6)	975 (85.7)

Between-Group Changes of Performance Measures

The primary study outcome measure, a composite of all 9 performance measures, showed significantly greater improvement of 21.7% in the intervention group from baseline to follow-up, compared with 8.3% in the control group (Table 2, Figs 1A and 1B).

Both groups demonstrated improvement in BMI-related measures. BMI documentation and interpretation was >95% at follow-up for both groups (Table 2). The intervention group improvement on the interpretation of BMI exceeded that of the control group but did not achieve statistical significance. Improvements to recommendations for obese and overweight children and the BMI composite measure were similar between groups.

A significant 29.4% improvement in the BP composite was seen in the intervention practices compared with the control practices. Recording of BP remained very high at follow-up for both groups (Table 2). Intervention group practices had a large improvement of BP interpretation from

<1% at baseline to 61.3% ($P < .001$), compared with no change (<1%) at follow-up for the control group. BP interpretation was the major determinant of the improvement seen in the BP composite measure performance. Changes in the rate of BP recommendations for children with elevated BP percentiles could not be assessed because of insufficient numbers at either baseline or follow-up evaluations.

Tobacco exposure assessment for children ages 3 to 4 years showed minimal variability between baseline and follow-up evaluations and between intervention and control groups. Tobacco assessment of exposure and use for children ages 5 to 11 years improved for control and intervention practices; improvement was 30.3% greater in intervention practices ($P = .042$). Tobacco counseling for children ages 5 to 11 years improved minimally and did not vary between groups. There was no significant difference between groups in the tobacco composite measure (Table 2).

Influence of Patient and Practice Characteristics on Change in Performance

The analyses to examine the influence of patient and practice characteristics on changes in performance demonstrated statistically significant change in BP interpretation (estimate: -6.126 , $P < .001$) and tobacco exposure assessment and use in children ages 5 to 11 years (estimate: -1.474 , $P = .008$) for intervention practices. This outcome is the same as was found in the unadjusted analyses. No differences were seen based on practice or patient characteristics, although patient race was missing in nearly two-thirds of the records, precluding an analysis based on this variable.

DISCUSSION

We developed and implemented a practice QI intervention to improve care related to BMI, BP, and tobacco in children ages 3 to 11 years. To our knowledge, this

is the first use of the American Board of Pediatrics' MOC Part 4 process in a cluster-randomized trial of guideline implementation. The overall improvement seen in the intervention, compared with control practices, was predominantly due to improved BP interpretation. BP interpretation was documented at baseline for <1% of patients in both control and intervention groups. During the study period, only intervention practices established and applied methods for BP interpretation. The assessment of tobacco exposure, tobacco use, and preventative counseling for children 5 to 11 years also increased significantly in the intervention practices compared with the control subjects. Measures of improved BMI-related care were similar between intervention and control groups, as was overall change in tobacco-related care. We surmised that this finding is because the control practices received copies of the guidelines, reports of baseline outcome data for their practice, and were motivated to enroll in a trial to improve CVD risk reduction. In addition, as a result of their affiliation with a practice-based research network, some of the control practices had previous experience and specific training in the use of QI methods. Previous research has shown that primary care visit use of BMI has risen from very low rates of 11% to ~90% during the last decade.^{29,30} Several QI collaboratives reported effective pediatric primary care-based interventions that improved the number of primary care practices that recorded BMI, provided guidance regarding obesity prevention, and identified and managed overweight or obese children.^{31,32}

To our knowledge, no previous studies describe strategies aimed at improving BP screening and interpretation in pediatric primary care practice. Our study improved BP interpretation from <1% to 60.5% in the intervention group. The intervention practices reported

TABLE 2 Measure Performance

Measure	Control, % (n/d)		Intervention, % (n/d)		Follow-up — Baseline Change (95% CI)		Difference of the Changes (95% CI)		P Value
	Baseline	F/U	Baseline	F/U	Control	Intervention	Intervention — Control		
BMI									
Record	83.3 (401/481)	96.6 (618/640)	92.9 (448/482)	98.1 (628/640)	13.2 (−0.6 to 27.1)	5.2 (2.4 to 8.1)	−8.0 (−24.5 to 8.4)	.333	
Interpret	88.6 (357/401)	95.2 (590/618)	75.5 (344/448)	97.4 (613/628)	6.3 (−2.0 to 14.5)	21.9 (7.1 to 36.8)	15.6 (−4.5 to 35.8)	.120	
Recommend	31.9 (31/100)	42.34 (74/175)	41.5 (34/82)	48.2 (87/168)	22.3 (−9.5 to 28.9)	6.7 (−12.1 to 27.4)	−15.6 (−34.1 to 30.0)	.897	
Composite	79.2 (778/982)	89.5 (1282/1433)	80.8 (826/1012)	92.1 (1322/1436)	10.3 (2.7 to 26.2)	10.5 (3.4 to 19.2)	−0.2 (−19.6 to 13.3)	.697	
BP									
Record	97.3 (468/481)	97.2 (622/640)	98.3 (474/482)	96.9 (620/640)	−0.1 (−2.0 to 1.8)	−1.5 (−3.1 to 0.2)	−1.4 (−4.3 to 1.6)	.356	
Interpret	0.4 (2/468)	0.6 (4/622)	0.2 (1/474)	61.3 (380/620)	0.2 (−1.1 to 1.5)	61.1 (42.9 to 78.1)	60.9 (39.7 to 80.9)	<.001	
Recommend	NA	NA	NA	100 (1/1)	NA	100	100	NA	
Composite	49.5 (470/949)	49.6 (626/1262)	49.7 (475/956)	79.2 (1001/1261)	0.1 (−0.8 to 0.9)	29.5 (20.7 to 38.4)	29.4 (19.2 to 39.8)	<.001	
Tobacco									
Assess exposure (3–4 y)	17.1 (28/164)	14.32/228	10	14.0 (32/228)	−3.1 (−5.4 to 13.7)	4 (−02.9 to 23.0)	7.1 (−12.9 to 24.6)	.528	
Assess exposure and Use (5–11 y)	0.6 (2/317)	21.4 (88/412)	3.4 (11/322)	49.1 (200/407)	15.4 (6.0 to 33.7)	45.7 (29.4 to 64.2)	30.3 (2.0 to 52.9)	.042	
Counsel (5–11 y)	4.7 (15/317)	9.7 40/412	2.8 (9/322)	13.3 (54/407)	−5.0 (−18.8 to 13.3)	11.5 (−09.8 to 22.3)	6.5 (−17.5 to 35.3)	.496	
Composite	5.6 (45/798)	15.2 (160/152)	4.5 (36/804)	27.6 (289/1047)	9.6 (−0.6 to 19.2)	23.1 (12.0 to 34.3)	13.5 (−3.6 to 31.2)	.115	
All measures									
Composite	47.4 (1293/2729)	55.2 (2068/3747)	48.2 1357/2772	69.8 (2612/3747)	8.3 (0.8 to 13.9)	21.7 (15.3 to 28.2)	13.4 (3.5 to 23.3)	.010	

CI, confidence interval; F/U, follow-up; NA, not available; n/d, numerator/denominator.

a variety of strategies to improve interpretation of BP, including the use of the study clinical decision support tool in practice workflow, posting BP charts in the examining room or incorporating them in their EMR. Documentation of assessment and counseling for second-hand smoke exposure occurs at a low number (4%) of pediatric health supervision visits.³³ Baseline assessments of compliance with guidelines were somewhat higher and improved during the intervention period (Table 1).

We used a “virtual” collaborative approach to the use of tools and strategies to improve performance. Our study indicates that practices benefit from having support to implement changes in risk factors that are not frequently addressed. BMI calculation and interpretation was already occurring at the practices. However, clinical decision support and other tools, as well as QI support, likely facilitated the improvement in BP interpretation in the intervention practices. The QI methods used were based on evidence to promote practice change, including academic detailing and collaborative learning.^{20,23,27} A point-of-care clinical decision support tool was designed and deployed to address the complexity of the guidelines and the required calculations that are necessary for efficient implementation. Questions remain about the extent to which the use of the entire set of tools alone or a less intense supported intervention will be sufficient to enhance guideline adoption among pediatric clinicians.

This study has several limitations. Because of its relatively short duration, the study evaluated practice processes and not patient behavior change that might result from those processes. This study was a nonblinded controlled trial of guideline implementation of 3 specific areas of the pediatric risk reduction guidelines. Although the baseline chart abstractions were blinded to the assignment of control and intervention

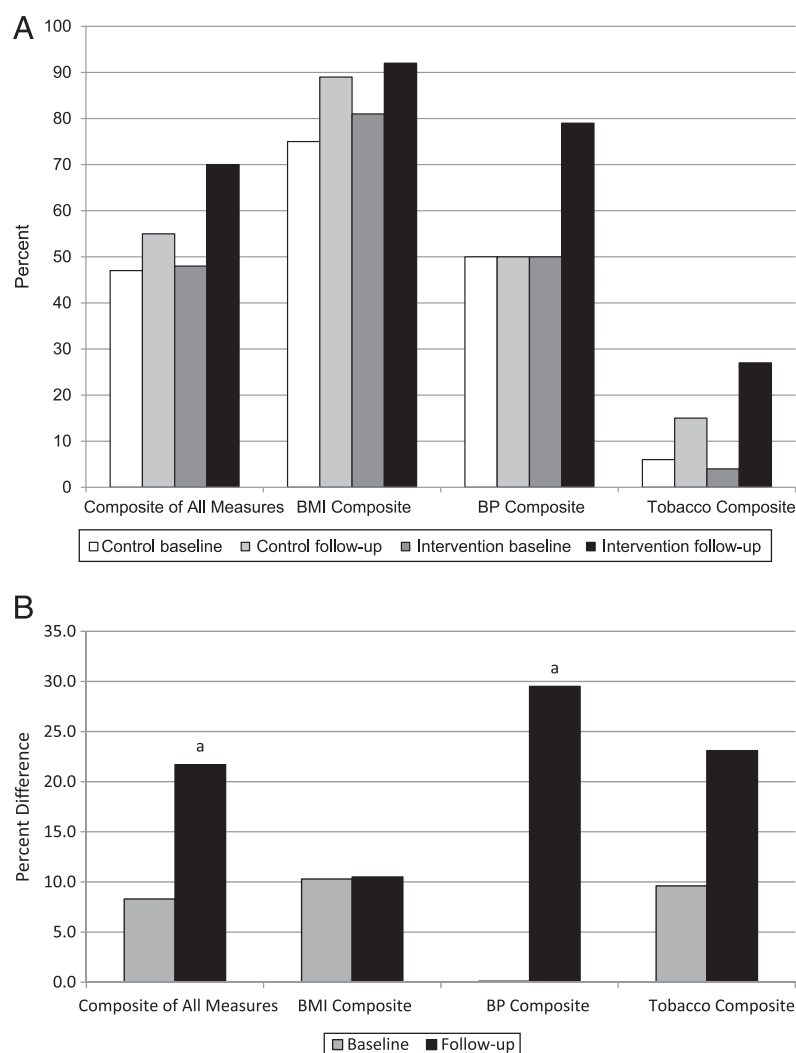


FIGURE 1

A, Composite measure results overall and according to condition. B, Improvement in the intervention group compared with the control group at baseline and follow-up. ^aSignificant improvement compared with the control group.

practices, postintervention chart abstraction was not blinded and may potentially impact the abstraction process. Clinicians at control practices received baseline performance data for their practice and National Heart, Lung, and Blood Institute guideline summary and

slide sets. Control group clinicians may have implemented changes in response to this information, which may account for the changes seen from the baseline to follow-up chart abstractions even though guideline information alone is not thought to be sufficient for adoption.^{20,23}

Participating practices may have had experience with practice-based research and thus may not be representative of pediatric practices in other environments. However, we recruited a relatively large number of practices from 2 very different geographic areas to address generalizability of the findings. Finally, other local efforts to improve obesity- and tobacco-related care may have had an effect on the participating practices. We are not aware of any specific effort related to BP in the geographic areas of the participating networks. Any outside influences likely would have affected intervention and control practices similarly.

CONCLUSIONS

This study demonstrated that a multifaceted intervention facilitates successful adoption of guideline components that can be applied to accelerate adoption of new guidelines. Participation in MOC Part 4 provided an incentive to participate. Both intervention and control practices improved care across many of the outcomes measured; however, the intervention practices showed greater improvement than the control practices in the overall composite measure and particularly in interpretation of BP. Larger scale interventions are needed to assess the generalizability of the tools and strategies employed in this study.

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