NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Review of Diagnostics Guidance DG9; EGFR-TK mutation testing in adults with locally advanced or metastatic non-small-cell lung cancer

Final recommendation post consultation
Transfer the guidance to the 'static guidance' list.

1. Background

This guidance was issued in August 2013.

At the GE meeting of 3 January 2017 it was agreed that we would consult on the recommendations made in the GE proposal paper. A four week consultation has been conducted and the responses are presented below.

2. Proposal put to stakeholders

Transfer the guidance to the 'static guidance' list.

3. Rationale for selecting this proposal

Changes in clinical practice, technology costs or evidence that would lead to a change in the recommendations of the original guidance have not been identified. It is therefore proposed that the guidance is placed on the static list. NICE is aware that plasma samples are sometimes used for testing EGFR mutations when no biopsy sample is available. The therascreen EGFR Plasma RGQ PCR Kit (Qiagen) and the cobas EGFR Mutation Test v2 (Roche Diagnostics Ltd) for use with circulating-free tumour DNA from plasma will be considered for Medtech innovation briefings.

4. Summary of consultation comments

Comments received during consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the comments received, and are not endorsed by NICE, its officers or advisory committees.

Respondent: NHS Professional **Response to proposal:** Agree I am writing this email to state that having reviewed the documentation including the more recent development of plasma DNA testing I support that the guidance can be moved to the static category. It is however important that plasma is a recognised DNA source and reimbursed in the same way as tissue DNA based testing.	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE.

Respondent: Royal Surrey County Hospital NHS Foundation Trust **Response to proposal:** Disagree The review has not taken into account the recent advances in the use of cell-free plasma samples for EGFR mutation testing in patients from whom it is not possible to acquire a cytology sample or a biopsy and therefore does not reflect current practice	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE. The population included in the scope for DG9 was defined as "*Adults with previously untreated, locally advanced or metastatic (stage III or IV) NSCLC of any histological subtype, with either a biopsy sample or a cytology sample available for EGFR-TK mutation testing*". The use of EGFR mutation testing for people with no biopsy or cytology sample available for testing would be beyond the scope of an update for this guidance. In order to keep a NICE diagnostics assessment to a reasonable size, some populations in which the test can be used may not be included in the scope (as set out in the diagnostics assessment manual, section 12.1). Importantly, the exclusion of patients from the scope should not be taken to mean that the test is inappropriate for these patients. NICE is aware of the advances in the use of circulating-free tumour DNA derived from either serum or plasma samples to test for EGFR mutations. These tests will be considered for Medtech innovation briefings.

Respondent: Royal Surrey County Hospital NHS Foundation Trust **Response to proposal:** No comment There is now clinical evidence for further assessment of EGFR status if the patient's disease progresses following first-line EGFR TKI. This testing is now routinely being requested of my department	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE. Osimertinib has been recommended as an option for use within the Cancer Drugs Fund (NICE TA 416). The costs of testing for T790M mutations (using either tissue biopsy or plasma testing) were included in cost-effectiveness modelling for this assessment. Therefore testing for this mutation, combined with treatment when relevant, has already been shown to be cost effective and is recommended by NICE in the context of the main recommendation in TA416.

Respondent: Royal Surrey County Hospital NHS Foundation Trust **Response to proposal:** Disagree The review refers to the use of circulating DNA in plasma but indicates that the scope of DG9 does not cover guidance relating to this situation; potentially NICE should widen the scope to include this or issue separate recommendations to cover both these scenarios.	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE. In order to keep a NICE diagnostics assessment to a reasonable size, some populations in which the test can be used may not be included in the scope (as set out in the diagnostics assessment manual, section 12.1). Importantly, the exclusion of patients from the scope should not be taken to mean that the test is inappropriate for these patients. NICE is aware of the advances in the use of circulating-free tumour DNA derived from either serum or plasma samples to test for EGFR mutations. These tests will be considered for Medtech innovation briefings.

Respondent: British Thoracic Oncology Group **Response to proposal:** No comment Clinical adoption of testing methodology for EGFR mutations is broader in terms of the range of technologies used in the NHS, compared to the list analysed in the document. There is a belief, with evidence to support it, that the method used to detect the mutation is not so relevant *when a mutation is detected* and that the control of this variation in practice is driven by performance in external quality assurance schemes.	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE. Tests, and test strategies, are recommended as options, when used in accredited laboratories participating in an external quality assurance scheme.

Respondent: British Thoracic Oncology Group **Response to proposal:** Disagree Some laboratories may consider using a plasma based cfDNA sample for testing – PRIOR TO ANY THERAPY – if there is no possibility of a tissue sample for testing being available. These patients WOULD fall within the scope of DG9	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE. The population included in the scope for DG9 was defined as "*Adults with previously untreated, locally advanced or metastatic (stage III or IV) NSCLC of any histological subtype, with either a biopsy sample or a cytology sample available for EGFR-TK mutation testing*". The use of EGFR mutation testing for people with no tissue sample available for testing would be beyond the scope of an update for this guidance. In order to keep a NICE diagnostics assessment to a reasonable size, some populations in which the test can be used may not be included in the scope (as set out in the diagnostics assessment manual, section 12.1). Importantly, the exclusion of patients from the scope should not be taken to mean that the test is inappropriate for these patients. NICE is aware of the advances in the use of circulating-free tumour DNA derived from either serum or plasma samples to test for EGFR mutations. These tests will be considered for Medtech innovation briefings.

Respondent: British Thoracic Oncology Group **Response to proposal:** No comment Some laboratories will use a so-called next generation sequencing strategy – PRIOR TO ANY THERAPY – to cover EGFR mutations amongst a number of other mutations covered by the test in use. These patients WOULD fall within the scope of DG9. I note reference to the Ion Torrent (Life Tech) panel on page 5, as one such approach.	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE. Next-generation sequencing was included in the assessment for DG9. However, the committee found that there was insufficient evidence on the clinical- and cost-effectiveness of this method to make a recommendation for its use (see recommendation 1.2). The search strategies from the original assessment were re-run for the review of DG9. No studies were identified on next-generation sequencing that provided enough data to inform an update.

Respondent: British Thoracic Oncology Group **Response to proposal:** No comment. Some laboratories will use immunohistochemistry to identify mutant protein in samples which have failed, or are predicted likely to fail, to give a satisfactory EGFR mutation test. These approaches lack sensitivity for ex19 mutations.	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE.

Respondent: British Thoracic Oncology Group **Response to proposal:** No comment I am unsure as to the mechanism for appraisal of new technology, including those mentioned in 2-4, once the document is declared 'static'. It would seem appropriate that these issues are reviewed from time to time	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE. If new evidence becomes available, guidance that has been placed on the static list can be transferred back to the active list for further appraisal. In addition, 5 years after guidance is added to the static list, NICE undertakes a 'static list review', that is, it considers whether a full review is required.

Respondent: British Thoracic Oncology Group **Response to proposal:** No comment. How does this document becoming 'static' impact on the practice of testing samples taken after relapse on EGFR TKI? This testing may well use the same technologies described in DG9 but it more likely to embrace new approaches, most specifically the use of cfDNA from plasma or even urine as a source of DNA. I acknowledge that this testing scenario is not strictly within the scope of DG9 but this omission will cause confusion and concern in the community.	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE. The recommendations in DG9 only relate to testing for EGFR‑TK mutations in the tumours of adults with untreated non-small-cell lung cancer that has spread. The use of tests or methods to monitor EGFR-TK status during treatment are beyond the scope of this guidance. Further, osimertinib has been recommended as an option for use within the Cancer Drugs Fund (NICE TA 416). The costs of testing for T790M mutations (using either tissue biopsy or plasma testing) were included in cost-effectiveness modelling for this assessment. Therefore testing for this mutation, combined with treatment when relevant, has already been shown to be cost effective and is recommended by NICE in the context of the main recommendation in TA416.

Respondent: British Thoracic Oncology Group **Response to proposal:** No comment It is always worth noting that when assessing test performance, the quality of samples used, including tumour content, can be a major confounding factor in test outcome results. Depending on the nature of any comparisons being made in a study, and how the samples were acquired and distributed between testing platforms, this effect can be significant.	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE.

Respondent: AstraZeneca UK Ltd **Response to proposal:** Disagree AstraZeneca are grateful for the opportunity to provide comments on the review proposal for Diagnostic Guidance 9. AstraZeneca disagrees with the decision to transfer DG9 to the static list; as there have been significant advancements within this clinical setting that require the scope of DG9 to be amended to ensure the NHS has expert guidance across all aspects of EGFR mutation testing.	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE.

Respondent: AstraZeneca UK Ltd **Response to proposal:** Disagree Aligned to the comments above, the "original objective for guidance" needs to be amended to ensure the NHS is given guidance on the broader clinical context of EGFR testing. Including the points that: 1. There is no consideration within this review of clinical trial data for the EGFR mutation testing for T790M. This is a specific EGFR mutation that is being inconsistently tested for in the NHS, therefore requiring NICE guidance. 2. Since the last DG9 update osimertinib has been approved by the EMA for the treatment of adult patients with locally advanced or metastatic EGFR T790M mutation-positive non-small-cell lung cancer (NSCLC) [ref: TAGRISSO (osimertinib) Summary of product characteristics November 2016 https://www.medicines.org.uk/emc/medicine/31496]. 3. Osimertinib was recommended as an option for use within the Cancer Drugs Fund for treating locally advanced or metastatic EGFR T790M mutation-positive non-small-cell lung cancer in adults whose disease has progressed only: • after first-line treatment with an EGFR tyrosine kinase inhibitor and • If the conditions in the managed access agreement for osimertinib are followed. [TA416, October 2016 https://www.nice.org.uk/guidance/ta416/chapter/1-Recommendations 4. EGFR testing at the point of progression is now a critical aspect within this clinical setting and has been incorporated into other recent international guidelines [NCCN Clinical Practice Guidelines in Oncology 2016, ESMO Clinical Practice Guidelines 2016, International Association for the Study of Lung Cancer Guidelines 2016] **5.** Complimentary testing strategy recommending both tissue and plasma testing for EGFRm at primary diagnosis and EGFR T790M at disease progression to ensure all patients whose NSLC contains these mutations are correctly identified [NCCN Clinical Practice Guidelines in Oncology 2016, ESMO Clinical	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE. The population included in the scope for DG9 was defined as "*Adults with previously untreated, locally advanced or metastatic (stage III or IV) NSCLC of any histological subtype, with either a biopsy sample or a cytology sample available for EGFR-TK mutation testing*". The use of EGFR mutation testing to inform second, or later, line of treatment decisions would be beyond the scope of an update for this guidance. As noted, osimertinib has been recommended as an option for use within the Cancer Drugs Fund (NICE TA 416). The costs of testing for T790M mutations (using either tissue biopsy or plasma testing) were included in cost-effectiveness modelling for this assessment. Therefore testing for this mutation, combined with treatment when relevant, has already been shown to be cost effective and is recommended by NICE in the context of the main recommendation in TA416.

Practice Guidelines 2016, International Association for the Study of Lung Cancer Guidelines 2016]	

Respondent: AstraZeneca UK Ltd **Response to proposal:** No comment Research recommendations This section is not correctly numbered within the proposal document and is positioned between Section 3 and 4.	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE. Numbering of the research recommendations in this section are as per the recommendations for further research in DG9.

Respondent: AstraZeneca UK Ltd **Response to proposal:** No comment To ensure DG-9 encompasses recommendation across the breadth of this setting, we recommend that the following technologies are further researched: Next Generation Sequencing (NGS), droplet digital PCR (ddPCR), EGFR testing using urine samples, and EGFR testing using Cerebral Spinal Fluid (CSF).	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE. The search strategies from the original assessment were re-run for the review of DG9. No studies were identified that provided enough data to inform an update.

Respondent: AstraZeneca UK Ltd **Response to proposal:** No comment AstraZeneca also agree that a multivariate prediction model should be investigated further to ensure that all EGFRm patients are promptly identified and treated appropriately. This would result in a complimentary testing strategy recommending both tissue and plasma testing for EGFRm at primary diagnosis and EGFR T790M at disease progression to ensure all patients whose NSLC contains these mutations are correctly identified [NCCN Clinical Practice Guidelines in Oncology 2016, ESMO Clinical Practice Guidelines 2016, International Association for the Study of Lung Cancer Guidelines 2016]	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE. The population included in the scope for DG9 was defined as "*Adults with previously untreated, locally advanced or metastatic (stage III or IV) NSCLC of any histological subtype, with either a biopsy sample or a cytology sample available for EGFR-TK mutation testing*". The use of EGFR mutation testing for people with no tissue sample available for testing would be beyond the scope of an update for this guidance. In order to keep a NICE diagnostics assessment to a reasonable size, some populations in which the test can be used may not be included in the scope (as set out in the diagnostics assessment manual, section 12.1). Importantly, the exclusion of patients from the scope should not be taken to mean that the test is inappropriate for these patients. NICE is aware of the advances in the use of circulating-free tumour DNA derived from either serum or plasma samples to test for EGFR mutations. These tests will be considered for Medtech innovation briefings.

Respondent: AstraZeneca UK Ltd **Response to proposal:** Disagree EGFR-TK plasma testing is classified as a liquid biopsy procedure, therefore is within the current scope of DG-9 and should be incorporated.	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE. The population specified in the scope of DG9 refers to a person with a 'biopsy sample' available for testing, rather than a liquid biopsy sample.

Respondent: AstraZeneca UK Ltd **Response to proposal:** No comment The Tagrisso NICE recommendation needs to be added to the Relevant NICE work section : Osimertinib for treating locally advanced or metastatic EGFR T790M mutation-positive non-small-cell lung cancer [TA416] https://www.nice.org.uk/guidance/ta416/chapter/1-Recommendations	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE.

Respondent: Roche Diagnostics Ltd **Response to proposal:** Disagree We think the review is very narrowly scoped and fails to address two important populations for which clinical practice has changed since the original guidance was produced: patients who cannot provide a tissue sample or have an inadequate tissue sample, and patients who progress after first line EGFR TKI. We think it is important for NICE to either broaden the scope of this review or to issue separate recommendations for both of these populations. As stated in the review proposal, use of plasma testing is becoming more widespread. If not included here, there will continue to be lack of Guidance to the NHS on the full utility of EGFR mutation testing in both the first and second line treatment settings. This is compounded by the absence of guidance around EGFR mutation testing in the published Clinical Guideline on Lung cancer: diagnosis and management (CG121).	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE. In order to keep a NICE diagnostics assessment to a reasonable size, some populations in which the test can be used may not be included in the scope (as set out in the diagnostics assessment manual, section 12.1). Importantly, the exclusion of patients from the scope should not be taken to mean that the test is inappropriate for these patients. NICE is aware of the advances in the use of circulating-free tumour DNA derived from either serum or plasma samples to test for EGFR mutations. These tests will be considered for Medtech innovation briefings. Further, osimertinib has been recommended as an option for use within the Cancer Drugs Fund (NICE TA 416). The costs of testing for T790M mutations (using either tissue biopsy or plasma testing) were included in cost-effectiveness modelling for this assessment. Therefore testing for this mutation, combined with treatment when relevant, has already been shown to be cost effective.

Respondent: Roche Diagnostics Ltd **Response to proposal:** No comment We would appreciate confirmation that the acquisition costs associated with the cobas® EGFR Mutation Test will be redacted in the final publication of the proposal, as these were highlighted as commercial in confidence in our original evidence submission. Furthermore, we perceive that highlighting the charged price used for modelling in the original assessment for the cobas® EGFR Mutation Test only (i.e. not listing charges for any of the other EGFR tests), puts us at a commercial disadvantage and was based on a limited and non-representative dataset.	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE. Information provided to NICE for this review of DG9 that was marked as confidential was redacted from the review proposal document. Costs for all EGFR tests used in modelling for DG9 (based on a survey of laboratories in England and Wales) are available in the published diagnostics assessment report for this topic.

Respondent: Roche Diagnostics Ltd **Response to proposal:** No comment No reference was made to the recent technology appraisal for osimertinib for treating locally advanced or metastatic EGFR T790M mutation-positive non-small-cell lung cancer in adults. The cobas® EGFR Mutation Test v2 detects TKI-resistance mutation T790M and is funded via the Cancer Drugs Fund. Therefore, omission of this technology appraisal within this review proposal does neglect a valid and relevant treatment pathway. We would draw the Committee's attention to the following publications: 1. Oxnard G.R., et al. Association Between Plasma Genotyping and Outcomes of Treatment With Osimertinib (AZD9291) in Advanced Non–Small-Cell Lung Cancer. Journal of Clinical Oncology 2016; 34(28): 3375 2. Thress K.S., et al. EGFR mutation detection in ctDNA from NSCLC patient plasma: A cross-platform comparison of leading technologies to support the clinical development of AZD9291. Lung Cancer 2015; 90: 509–515	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE. Osimertinib has been recommended as an option for use within the Cancer Drugs Fund (NICE TA 416). The costs of testing for T790M mutations (using either tissue biopsy or plasma testing) were included in cost-effectiveness modelling for this assessment. Therefore testing for this mutation, combined with treatment when relevant, has already been shown to be cost effective and is recommended by NICE in the context of the main recommendation in TA416.

Respondent: Roche Diagnostics Ltd **Response to proposal:** No comment Additionally, we would draw the Committee's attention to the following publications: **1.** Mok T., et al Detection and Dynamic Changes of EGFR Mutations from Circulating Tumor DNA as a Predictor of Survival Outcomes in NSCLC Patients Treated with First-line Intercalated Erlotinib and Chemotherapy. Clin Cancer Res 2015; 21(14): 3196–203	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE.

Respondent: Roche Diagnostics Ltd **Response to proposal:** No comment We do not agree with the sensitivity and specificity values reported for the cobas® EGFR Mutation Testing Kit based on the study by Benlloch, et al. and request revision based on the following points. While the U.S. Food and Drug Administration used Sanger sequencing as the reference method for new oncology tests such as the cobas® EGFR Mutation Test, they acknowledged that the Sanger sequencing has lower sensitivity and specificity than PCR-based oncology tests (please see Mansfield EA. FDA perspective on companion diagnostics. Clin Cancer Res. 2014; 20:1453-7.) The positive and negative percent agreements (PPA and NPA), such as reported by Benlloch et al, describe how well the cobas® EGFR Mutation Test results match Sanger sequencing test results or the LDT used in the study, however, the clinical validity or sensitivity and specificity of a test should be based on the ability of the test to correctly classify patient specimens and not based on PPA and NPA to a method with lower sensitivity and specificity. Given that massively parallel pyrosequencing is recognized to have higher sensitivity and specificity than Sanger sequencing, if we assume pyrosequencing results reflect the "true" mutation status of the specimen, then the tables below show the sensitivity and specificity comparisons between cobas® EGFR Mutation Test and Sanger sequencing based on adjudicated test results with massively parallel pyrosequencing (Benlloch, et al). We believe that the test performance of LDTs used for EGFR mutation testing is highly uncertain due to lack of evidence and variation between labs. The LDT used in the study conducted by Benlloch, et al. was developed for a clinical study. It is uncertain how well that particular LDT reflects the quality and test performance of the numerous different LDTs routinely developed across different laboratory settings. We do not believe it possible for any conclusions to be made about LDT test performance from the published literature due to the varying nature of the development process across different laboratories.	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE. The review proposal for DG9 presents data from Benlloch et al. (2014) as reported in the study. The reference standard used to assess the diagnostic accuracy of the cobas EGFR mutation testing kit is stated in the review proposal, as are the results of testing of any discordant results between the cobas test and the reference standard by using massively parallel pyrosequecing (section 6.3.4).

COBAS (vs. Sanger with MPP resolution of discordant results)

	Mutation	Wild Type	Total
Test +	141	1	142
Test -	3	257	260
Total	144	258	402

True Positive (Sensitivity)	0.979166667
False Negative	0.020833333
False Positive	0.003875969
True Negative (Specificity)	0.996124031

SANGER (vs. cobas with MPP resolution of discordant results)

	Mutation	Wild Type	Total
Test +	115	1	116
Test -	29	257	286
Total	144	258	402

True Positive (Sensitivity)	0.798611111
False Negative	0.201388889
False Positive	0.003875969
True Negative (Specificity)	0.996124031

Respondent: Roche Diagnostics Ltd **Response to proposal:** No comment With regards to the recommendation that "studies directly comparing different EGFR-TK mutation test methods are performed" we would draw the Committee's attention to the following publication: Lopez-Rios F., et al. Comparison of molecular testing methods for the detection of EGFR mutations in formalin-fixed paraffin-embedded tissue specimens of non-small cell lung cancer. J Clin Pathol 2013;66:381–385. Additionally, the requirement for EGFR-TK mutations test methods to be included in studies that link to patient outcomes (i.e. end-to-end studies), will be difficult to achieve, particularly given the length of time EGFR testing has already been on the market. Linked evidence approaches should continue to be available to diagnostic technologies for reasons outlined in the Diagnostics Assessment Programme manual. The research recommendations listed set a high and potentially unattainable bar for the evidence requirements necessary to trigger a re-review of the Guidance. A further minor point is that sections 7.1 and 7.2 appear misplaced in the document (on page 2 rather than page 10).	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE.

Respondent: Roche Products Ltd **Response to proposal:** Disagree We like to echo the comments made in the Roche Diagnostics submission and make a few additional comments.	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE.

Respondent: Roche Products Ltd **Response to proposal:** Disagree We are of the view that this review has failed to take into account a number of critical changes to clinical practice that would have necessitated a review of this guideline. Please find attached the most recent, NCCN guidelines for NSCLC that state that Broad Molecular Profiling should be used for EGFR testing.	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE. The scope of DG9 focuses on EGFR-TK mutation testing; consideration of broader scope testing of NSCLC samples (i.e. to assess the status of multiple genes in addition to EGFR) would be beyond the scope of an update for this guidance. The use of technologies (next-generation sequencing) that can be used for broader testing of samples was considered in DG9 (and this review) in the context of EGFR testing.

Respondent: Roche Products Ltd **Response to proposal:** No comment In addition, please find attached the Alexander Drilon paper that highlights the large numbers of patients missed through current testing methods that are picked up by broad molecular profiling.	**Comments from the Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE.

Paper signed off by: Mirella Marlow, 21 February 2017

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Confidential information is highlighted and underlined.