

National Institute for Health and Care Excellence

4-year surveillance (2016) – [Idiopathic pulmonary fibrosis in adults](#) (2016) NICE guideline CG163

Appendix B: stakeholder consultation comments table

Consultation dates: 9 to 22 December 2016

Do you agree with the proposal not to update the guideline?			
Stakeholder	Overall response	Comments	NICE response
Total Health Matters!	No	Because of a serious omission	Thank you for your comment. We are unclear as to the reasons to which you disagree with the proposal not to update the guideline.
University Hospital Of South Manchester NHS Foundation Trust (HQ)	No	Need to update in accordance with NICE appraisal of nintedanib so need to include both pirfenidone and nintedanib in the Disease modifying section.	Thank you for your comment. We will amend the guideline to add a cross-referral to NICE TA379 published January 2016 (Nintedanib for treating idiopathic pulmonary fibrosis) in the disease-modifying pharmacological interventions section in recommendations 1.5.11 to 1.5.15 NICE guideline CG163. A cross referral has been made to NICE technology appraisal guidance TA282 (pirfenidone for the management of idiopathic pulmonary fibrosis) in recommendation 1.5.11 NICE guideline CG163.
British Thoracic Society	No	There have been a number of significant changes since the guidelines were last reviewed and the British Thoracic Society strongly supports an update to this important guideline.	Thank you for your comment. We will amend the guideline to add a cross-referral to NICE TA379 published January 2016

		<p style="text-align: center;">Nintedanib</p> <p>Please ensure appropriate sign-posting of TA379</p> <p style="text-align: center;">N-acetyl cysteine</p> <p>The PANTHER trial has shown NAC to be ineffective and we believe the guideline should state this more overtly.</p>	<p>(Nintedanib for treating idiopathic pulmonary fibrosis) in recommendations 1.5.11 to 1.5.15 NICE guideline CG163. NICE TA379 is included in the NICE guideline CG163 pathway.</p> <p>The evidence from current surveillance review suggests that N-acetylcysteine had no beneficial effect on changes in FVC, changes in predicted carbon monoxide diffusing capacity, rates of adverse events, or death rates. However a significant effect in favour of N-acetylcysteine was found on decreases in percentage of predicted vital capacity and 6 minutes walking test distance.</p> <p>CG163 recommends (1.5.13) 'advise the person that oral N-acetylcysteine is used for managing IPF, but its benefits are uncertain'. CG163 considered early evidence from the PANTHER trial that suggested that N-acetylcysteine was 'relatively safe in therapeutic doses'.</p> <p>Because the recommendation already acknowledges uncertainty about the benefits of this drug, and no new safety concerns have been raised about its use, therefore there is no impact on current recommendations at this time. This area will be examined again at the next surveillance review of the guideline.</p>
Royal College of Nursing	No	It is important to recognise that clinicians must spend adequate time with people with IPF. Their prognosis is poor. It is essential that patients' and carers' values and preferences are established, so that the appropriate course of action can be decided.	Thank you for your comment. Current recommendations promote a supportive approach coordinated by a multidisciplinary team with appropriate skills. No new

			<p>evidence was identified in this area which impacted on current recommendations.</p> <p>NICE has also produced guidance on the components of good patient experience in adult NHS services. The related recommendations are in Patient experience in adult NHS services (NICE clinical guideline 138).</p>
Association of Respiratory Nurse Specialists	No	<p>It is important to recognise that clinicians must spend adequate time with patients with IPF. Their prognosis is poor. It is essential that patients and carers' values and preferences are established, so that the appropriate course of action can be decided.</p>	<p>Thank you for your comment. Current recommendations promote a supportive approach coordinated by a multidisciplinary team with appropriate skills. No new evidence was identified in this area which impacted on current recommendations.</p> <p>NICE has also produced guidance on the components of good patient experience in adult NHS services. The related recommendations are in Patient experience in adult NHS services (NICE clinical guideline 138).</p>
NHS England	No	<p>The guidance with regards to Nintedanib needs strengthening in line with TA379</p> <p>Needs a clearer statement around the lack of benefit of NAC</p>	<p>Thank you for your comment. We will amend the guideline to add a cross-referral to NICE TA379 published January 2016 (Nintedanib for treating idiopathic pulmonary fibrosis) in recommendations 1.5.11 to 1.5.15 NICE guideline CG163.</p> <p>The evidence from surveillance reviews suggests that N-acetylcysteine had no beneficial effect on changes in FVC, changes in predicted carbon monoxide diffusing capacity, rates of adverse events, or death rates. However a significant effect in favour of N-acetylcysteine was found on decreases in percentage of predicted vital</p>

			<p>capacity and 6 minutes walking test distance.</p> <p>CG163 recommends (1.5.13) 'advise the person that oral N-acetylcysteine is used for managing IPF, but its benefits are uncertain'. CG163 considered early evidence from the PANTHER trial that suggested that N-acetylcysteine was 'relatively safe in therapeutic doses'.</p> <p>Because the recommendation already acknowledges uncertainty about the benefits of this drug, and no new safety concerns have been raised about its use, therefore there is no impact on current recommendations at this time. This area will be examined again at the next surveillance review of the guideline.</p>
Action for Pulmonary Fibrosis	Yes	No comment	Thank you for your comment.

Do you agree with the proposal to remove the research recommendation:

What is the value of bronchoalveolar lavage in people in whom idiopathic pulmonary fibrosis is considered the most likely diagnosis when clinical and CT findings are insufficient to support a confident diagnosis?

Stakeholder	Overall response	Comments	NICE response
Total Health Matters!	No comment	No comment	Thank you for your comment.
University Hospital Of South Manchester NHS Foundation Trust (HQ)	YES	I don't think this is a key research question	Thank you for your comment.
British Thoracic Society	Yes	No comment	Thank you for your comment.

Royal College of Nursing	Yes	The diagnosis of IPF depends upon the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) in patients not subjected to lavage/surgical lung biopsy. This is in addition to expert decision making of the multidisciplinary team (MDT).	Thank you for your comment.
Association of Respiratory Nurse Specialists	Yes	The diagnosis of IPF depends upon the presence of a UIP pattern on high-resolution computed tomography (HRCT) in patients not subjected to lavage/surgical lung biopsy. This is in addition to expert decision making of the MDT.	Thank you for your comment.
NHS England	Yes	No comment	Thank you for your comment.
<p>Do you agree with the proposal to remove the research recommendation:</p> <p>What is the value of surgical lung biopsy in people in whom idiopathic pulmonary fibrosis is considered the most likely diagnosis when clinical and CT findings are insufficient to support a confident diagnosis?</p>			
Stakeholder	Overall response	Comments	NICE response
Total Health Matters!	No comment	No comment	Thank you for your comment.
University Hospital Of South Manchester NHS Foundation Trust (HQ)	?		Thank you for your comment, unfortunately without further information as to how this relates to the research recommendation we are unable to investigate further.
British Thoracic Society	Yes	No comment	Thank you for your comment.
Royal College of Nursing	Yes	Where computerised tomography scan (CT) findings are unclear, a holistic assessment of the patient is made by the MDT to consider the risks of performing the surgical lung biopsy in order to make the definite diagnosis (in particular, age and disease severity). The patient is also informed of the risks associated with the procedure.	Thank you for your comment.
Association of Respiratory Nurse Specialists	Yes	Where CT findings are unclear, a holistic assessment of the patient is made by the MDT to consider the risks of performing the surgical lung biopsy in order to made the definite diagnosis (in particular, age and disease severity). The patient is also informed of the risks associated with the procedure.	Thank you for your comment.

NHS England	Yes	No comment	Thank you for your comment.
Do you agree with the proposal to remove the research recommendation:			
Does pulmonary rehabilitation improve outcomes for people with idiopathic pulmonary fibrosis?			
Stakeholder	Overall response	Comments	NICE response
Total Health Matters!	No	Because there is a growing body of evidence that breath training (either based on the Buteyko Method or Papworth Method) improves the functioning of residual undamaged lung areas.	Thank you for your comment. Based on stakeholder feedback we will retain the research recommendation at this time and review it again at the next surveillance review.
University Hospital Of South Manchester NHS Foundation Trust (HQ)	No	Still needs ongoing assessment and there are many questions regarding home programmes, sustainability, should rehabilitation occur separate to other respiratory disease patients etc that need to be assessed and addressed	Thank you for your comment. Based on stakeholder feedback we will retain the research recommendation at this time and review it again at the next surveillance review.
British Thoracic Society	Yes	No comment	Thank you for your comment.
Royal College of Nursing	No	Pulmonary Rehabilitation is evidenced based for those with Interstitial lung disease (ILD) and has shown similar responses to non-Chronic Obstructive Pulmonary Disease (COPD) patients. It has shown to improve both function and quality of life. Patient experience is a relevant and important outcome for these patients.	Thank you for your comment. Based on stakeholder feedback we will retain the research recommendation at this time and review it again at the next surveillance review.
Association of Respiratory Nurse Specialists	No	Pulmonary Rehabilitation is evidenced based for those with ILD and has shown similar responses to non COPD patients. It has shown to improve both function and quality of life. Patient experience is a relevant and important outcome for these patients.	Thank you for your comment Based on stakeholder feedback we will retain the research recommendation at this time and review it again at the next surveillance review.
NHS England	Yes	No comment	Thank you for your comment

Do you agree with the proposal to remove the research recommendation:

Does ambulatory oxygen improve outcomes in idiopathic pulmonary fibrosis?

Stakeholder	Overall response	Comments	NICE response
Total Health Matters!	Yes	Because the problem may lie in poor gas exchange that depends in on the Bohr effect, CO2 is as important as O2.	Thank you for your comment. Upon identification of an on-going trial (Auto-titrating Oxygen in Chronic Respiratory Failure (AS11)), we will retain the research recommendation at this time and review it again at the next surveillance review.
University Hospital Of South Manchester NHS Foundation Trust (HQ)	No	Still as yet unanswered. There is an RCT that has just completed recruitment addressing this question	Thank you for your comment. Based on the highlighted trial (Auto-titrating Oxygen in Chronic Respiratory Failure (AS11)) we will retain the research recommendation at this time and review it again at the next surveillance review.
British Thoracic Society	Yes	No comment	Thank you for your comment. Upon identification of an on-going trial (Auto-titrating Oxygen in Chronic Respiratory Failure (AS11)) we will retain the research recommendation at this time and review it again at the next surveillance review.
Royal College of Nursing	Yes	There is neither evidence to support outcomes currently, nor is it correlated to improving quality of life. Anecdotally, oxygen is prescribed to aid function and provide protection to other organs.	Thank you for your comment. Upon identification of an on-going trial (Auto-titrating Oxygen in Chronic Respiratory Failure (AS11)) we will retain the research recommendation at this time and review it again at the next surveillance review.

Association of Respiratory Nurse Specialists	Yes	There is no evidence to support outcomes currently. Nor is it correlated to improving quality of life. Anecdotally, oxygen is prescribed to aid function and provide protection to other organs.	Thank you for your comment. Upon identification of an on-going trial (Auto-titrating Oxygen in Chronic Respiratory Failure (ASI1)) we will retain the research recommendation at this time and review it again at the next surveillance review.
NHS England	Yes	No comment	Thank you for your comment. Upon identification of an on-going trial (Auto-titrating Oxygen in Chronic Respiratory Failure (ASI1)) we will retain the research recommendation at this time and review it again at the next surveillance review.

Do you agree with the proposal to remove the research recommendation:

Is anti-reflux therapy an effective treatment for idiopathic pulmonary fibrosis?

Stakeholder	Overall response	Comments	NICE response
Total Health Matters!	Yes	I fail to see the significant link.	Thank you for your comment. Upon identification of an on-going trial (Pilot Trial Of Omeprazole in Idiopathic Pulmonary Fibrosis (IPF) (PPIPF)) we will retain the research recommendation at this time and review it again at the next surveillance of the guideline.
University Hospital Of South Manchester NHS Foundation Trust (HQ)	NO	Still an important unanswered question	Thank you for your comment. Upon identification of an on-going trial (Pilot Trial Of Omeprazole in Idiopathic Pulmonary Fibrosis (IPF) (PPIPF)) we will retain the research recommendation at this time and review it again at the next surveillance of the guideline.

British Thoracic Society	No	<p>“RR – 05 Is anti-reflux therapy an effective treatment for idiopathic pulmonary fibrosis?” No new evidence relevant to the research recommendation was found and no ongoing studies were identified. Surveillance decision This research recommendation should be removed from the NICE version of the guideline and the NICE research recommendations database because further research is unlikely to impact on the guideline.”</p> <p>The Newcastle group are currently researching this area (CI Professor John Simpson) – we propose this stays for the time being.</p>	Thank you for your comment. In the view of the highlighted on-going trial (Pilot Trial Of Omeprazole in Idiopathic Pulmonary Fibrosis (IPF) (PPIPF)) we will retain the research recommendation at this time and review it again at the next surveillance of the guideline.
Royal College of Nursing	Yes	There is no evidence to suggest anti-reflux therapy is a treatment/improves prognosis for IPF. It does however provide valuable symptom control and there is a suggestion that it prevents aspiration.	Thank you for your comment. Upon identification of an on-going trial (Pilot Trial Of Omeprazole in Idiopathic Pulmonary Fibrosis (IPF) (PPIPF)) we will retain the research recommendation at this time and review it again at the next surveillance of the guideline.
Association of Respiratory Nurse Specialists	Yes	There is no evidence to suggest anti-reflux therapy is a treatment/improves prognosis for IPF. It does however provide valuable symptom control, and there is a suggestion that it prevents aspiration.	Thank you for your comment. Upon identification of an on-going trial (Pilot Trial Of Omeprazole in Idiopathic Pulmonary Fibrosis (IPF) (PPIPF)) we will retain the research recommendation at this time and review it again at the next surveillance of the guideline.
NHS England	Yes	No comment	Thank you for your comment. Upon identification of an on-going trial (Pilot Trial Of Omeprazole in Idiopathic Pulmonary Fibrosis (IPF) (PPIPF)) we will retain the research recommendation at this time and review it again at the next surveillance of the guideline.

Do you have any comments on areas excluded from the scope of the guideline?

Stakeholder	Overall response	Comments	NICE response
Total Health Matters!	Yes	The Buteyko Method training give improved ventilation for COPD or emphysema patients therefore would it not merit more research for idiopathic pulmonary fibrosis?	Thank you for your comment. The area has been captured in the scope of the guideline. CG163 recommends offering pulmonary rehabilitation including exercise and educational components tailored to the needs of people with idiopathic pulmonary fibrosis (1.5.3).
University Hospital Of South Manchester NHS Foundation Trust (HQ)		Nintedanib	Thank you for your comment. We will amend the guideline to add a cross-referral to NICE TA379 published January 2016 (Nintedanib for treating idiopathic pulmonary fibrosis) in recommendations 1.5.11 to 1.5.15 NICE guideline CG163.
British Thoracic Society	No	No comment	Thank you for your comment.
Royal College of Nursing	Yes	Upon diagnosis these patients should be treated equivocal to patients with lung cancer, and should be seen as soon as possible for a decision upon targeted therapy.	Thank you for your comment. The area has been captured in the scope of the guideline. CG163 recommends offering best supportive care that tailored to disease severity, rate of progression, and the person's preference to people with IPF from the point of diagnosis (1.5.5 to 1.5.10).
Association of Respiratory Nurse Specialists	Yes	Upon diagnosis these patients should be treated equivocal to patients with lung cancer, and should be seen as soon as possible for a decision upon targeted therapy.	Thank you for your comment. Thank you for your comment. The area has been captured in the scope of the guideline. CG163 recommends offering best supportive care that tailored to disease severity, rate of progression, and the person's preference to people with IPF from the point of diagnosis (1.5.5 to 1.5.10).

NHS England	No	No comment	Thank you for your comment.
Do you have any comments on equalities issues?			
Stakeholder	Overall response	Comments	NICE response
Total Health Matters!	No	No comment	Thank you for your comment.
University Hospital Of South Manchester NHS Foundation Trust (HQ)	No	No comment	Thank you for your comment.
British Thoracic Society	Yes	Dr Felix Woodhead presented a poster at the BTS Winter Meeting (Dec 2016) on prescribing differences in pirfenidone depending on whether the local hospital prescribed or the patient had to travel to a prescribing centre. This has highlighted to us the issues of equality and the fact that this is enshrined in the NHS constitution. We'd like to bring this to the attention of NICE. (see below).	Thank you for your comment. NICE has also produced guidance on the components of good patient experience in adult NHS services (NICE clinical guideline 138). The guideline recommends that healthcare professionals should take into account the requirements of the Equality Act 2010 and make sure services are equally accessible to, and supportive of, all people using adult NHS services (1.1.6). The Equality Act 2010 covers nine protected characteristics: age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex and sexual orientation. Additionally, an equality impact assessment was carried out after development of the guideline recommendations. This document confirmed that the recommendations and quality statements have been formulated to promote equalities for all people who receive healthcare within the adult NHS services, irrespective of gender, ethnicity, disability, religion or beliefs, sexual

			<p>orientation and gender identity or socio-economic status. No information was identified through this surveillance review to change those conclusions.</p> <p>Thank you for the highlighted article. It will be included in summary of evidence at 4-year surveillance of CG163. However this article does not affect the overall impact on current recommendations.</p>
Royal College of Nursing	Yes	<p>There is a noted inequality and variation of services across the county outside of specialist centre areas. Access is poor.</p> <p>There is also noted inequality relating to patient information, in terms of availability for Asian and Indian patients, for example.</p>	<p>Thank you for your comment. NICE has also produced guidance on the components of good patient experience in adult NHS services (NICE clinical guideline 138). The guideline recommends that healthcare professionals should take into account the requirements of the Equality Act 2010 and make sure services are equally accessible to, and supportive of, all people using adult NHS services (1.1.6). The Equality Act 2010 covers nine protected characteristics: age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex and sexual orientation.</p> <p>Additionally, an equality impact assessment was carried out after development of the guideline recommendations. This document confirmed that the recommendations and quality statements have been formulated to promote equalities for all people who receive healthcare within the adult NHS services, irrespective of gender, ethnicity, disability, religion or beliefs, sexual orientation and gender identity or socio-economic status. No information was</p>

			identified through this surveillance review to change those conclusions.
Association of Respiratory Nurse Specialists	Yes	There is noted inequality of services across the county outside of specialist centre areas. Access is poor. There is also noted inequality relating to patient information, in terms of availability for Asian and Indian patients, for example.	Thank you for your comment Thank you for your comment. NICE has also produced guidance on the components of good patient experience in adult NHS services (NICE clinical guideline 138). The guideline recommends that healthcare professionals should take into account the requirements of the Equality Act 2010 and make sure services are equally accessible to, and supportive of, all people using adult NHS services (1.1.6). The Equality Act 2010 covers nine protected characteristics: age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex and sexual orientation. Additionally, an equality impact assessment was carried out after development of the guideline recommendations. This document confirmed that the recommendations and quality statements have been formulated to promote equalities for all people who receive healthcare within the adult NHS services, irrespective of gender, ethnicity, disability, religion or beliefs, sexual orientation and gender identity or socio-economic status. No information was identified through this surveillance review to change those conclusions.
NHS England	No	No comment	Thank you for your comment.

