PROJECT INITIATION DOCUMENT

Project title: Identification and optimisation of care for patients at risk of respiratory admission through an enhanced integrated multi-disciplinary team

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SUMMARY	A Joint Working Project between Oxfordshire CCG (OCCG) and Boehringer Ingelheim (BI) to develop an enhanced integrated multi-disciplinary respiratory team (IRT) to: • Increase and improve accurate, timely diagnosis of respiratory disease • Identify a cohort of patients who are at risk of respiratory admissions • Optimise clinical management, and • Introduce early holistic and end of life care • Integrate the care of patients within primary & secondary care and community settings It is anticipated that this will achieve improved patient-centred care leading to: • A reduction in emergency respiratory admissions and 30-day readmissions in the IRT patient cohort (defined in Scope section) • A reduction of the deficit between registered and estimated COPD prevalence • A reduction in respiratory outpatient appointments within specified clinics • A reduction in ambulance call outs and emergency department attendances • An increase in smoking cessation in the IRT cohort • Better identification of end of life patients and/or patients needing supportive holistic care in IRT patient cohort with increased advance care planning • Improved identification and treatment of respiratory patients in IRT patient cohort with mental health problems, anxiety and depression in particular. • Improved quality of life, mental health, and self-care for patients and their carers BI and OCCG will jointly fund the IRT and will collaborate to evaluate clinical-, patient reported and health economic outcomes. This is in line with the principles of joint working endorsed by the Department of Health and as described in Clause 20 of the ABPI Code of Practice 2016 and supplementary documents. The project will start in November 2018 and project duration will be 15 months.
BACKGROUND:	1. Long term conditions (LTCs) are a significant burden to the NHS, with around 15 million people affected in England[1], consuming over 70% of primary and secondary care budgets[1]. 2. Chronic obstructive pulmonary disease (COPD) is a long-term condition and the second most common lung disease in the UK, affecting 1.2 million people[2]. The annual direct care costs of COPD in England are £1.5bn[3], a significant burden to the NHS. COPD is the second most common cause of emergency admission to hospital in adults in the UK[4]. 3. Oxfordshire currently has a COPD population of 9,897[5] and an Asthma population of 42,213[6]. 4. In the NHS RightCare Atlas of Variation 2012, Oxfordshire PCT was identified as being in the highest quintile in England for the percentage of COPD emergency re-admissions to hospital within 30 days of discharge[7]. 5. Within its RightCare[8] cluster of similar CCGs, Oxfordshire has the second poorest ratio of reported to estimated prevalence of COPD (65.6%) which means there are an estimated 1,800 people who have undiagnosed COPD in Oxfordshire. Other quantified opportunities for improvement relating to adults include:

5.1. COPD diagnosis confirmed by spirometry
5.2. COPD patients who have had a review and breathlessness assessment
5.3. Asthma patients who have had a 12-month review
5.4. Acute lower respiratory – non-elective spend
5.5. Emergency admissions due to acute lower respiratory infections
5.6. Asthma mortality (all ages)

6. A recent audit[9] of a general practice in Oxford city (list size 8500 patients), found that only half of the emergency respiratory admissions (where patients had a diagnosed underlying respiratory pathology) were known to either the Community Respiratory Service or had been seen as an outpatient. The majority of these patients had a diagnosis of either COPD (51%) or asthma (32%). This suggests that there is an opportunity for the IRT to oversee the management of additional patients with significant respiratory disease in the primary care setting. Furthermore, one third of patients who had a respiratory admission did not have a recognised respiratory pathology and some of these patients are likely to have undiagnosed COPD. This represents another opportunity for improving patient care.

7. The project seeks to improve proactive management of a defined cohort of patients with respiratory disease in primary and community care. Current hospital data[10] suggests there are significant unplanned respiratory admissions taking place which is not optimal clinical management for the patient. The following hospital emergency department (ED), inpatient and outpatient data was provided by Oxford University Hospitals NHS Trust (OUHFT) as activity that could be impacted by the IRT defined within this project. The cohort of patients within the remit of the IRT and whose healthcare activity the IRT is estimated to be able to affect is known as the 'IRT cohort' throughout this document.

8. The defined patient cohort within the remit of the IRT will include:
   8.1. Patients with airways disease: Asthma and COPD
   8.2. Bronchiectasis patients not requiring intensive secondary care management
   8.3. End-stage Interstitial lung disease (ILD) patients including those with sarcoidosis
   8.4. Patients with neuromuscular disease or on home non-invasive ventilation (NIV) requiring physiotherapy input to optimise airways clearance and manage home NIV

Current Oxfordshire hospital activity

9. For the purpose of establishing the ED and non-elective inpatient hospital activity of the IRT cohort, the patients were identified by:

   9.1. Diagnoses with a primary inpatient diagnosis code of: **Asthma, Bronchiectasis, Bronchitis, COPD, Emphysema, Interstitial Lung Disease*, Sarcoidosis* and Wheezing**

   and

   9.2. Patients with **Pneumonia, Cough, Upper Respiratory Tract Infection, or Lower Respiratory Tract Infection** as their primary diagnosis, who also have a secondary diagnosis of one of the above.

10. *End stage ILD and Sarcoidosis – mostly Idiopathic Pulmonary Fibrosis (IPF) under palliative pathway from ILD service and not under ILD clinic active treatment with disease modifying drugs. Most of the IPF patients will be known already to the home oxygen team as they will be home oxygen patients. The IRT proposal extends their care to offer interventions to manage advanced breathlessness as well as to improve palliative care support and advance care planning to reduce hospital admissions. Care can be offered in conjunction with the ILD specialist nurses based in secondary care.

11. Figure 1[10] (below) shows adult non-elective (NEL) admissions (2017/18) of OCCG registered IRT cohort patients at all Trusts where there have been 30 or more admissions in the year. The data includes cost of NEL admissions and total length of stay (bed days). This data is from Secondary Uses Service (SUS) data processed by South Central and West Commissioning Support Unit (SCWCSU). 93% of admissions were at OUHFT and 4.8% of admissions were at Royal Berkshire NHS Foundation Trust (RBHFT). The admissions are split by the OCCG locality the patient is registered in. These are the NEL admissions that the IRT will be able to influence.

OCCG Locality	NEL Admissions	Cost	Bed Days
North East Oxfordshire	663	£1,549,152	3,146
North Oxfordshire	1,024	£2,211,812	4,916
Oxford City	1,367	£3,063,423	5,824
South East Oxfordshire	593	£1,604,536	4,060
South West Oxfordshire	930	£2,408,533	5,444
West Oxfordshire	583	£1,381,376	2,703
Undefined	*16*	*£51,340*	*78*
Total	**5,176**	**£12,270,172**	**26,171**

Figure 1 Adult non-elective (NEL) admissions (2017/2018) of OCCG registered IRT cohort patients at all trusts with 30 or more admissions.

12. Figure 2[10] (below) shows adult emergency department (ED) attendances (2017/18) of OCCG registered IRT cohort patients at OUHFT. Only OUHFT ED attendances are shown because the ED attendances at other Trusts are minimal. The data includes cost of ED attendances. This data is from SUS data processed by SCWCSU. The ED attendances are split by the OCCG locality the patient is registered in. These are the ED attendances that the IRT will be able to influence.

OCCG Locality	OUHFT ED Attendances	Cost
North East Oxfordshire	336	£53,773
North Oxfordshire	665	£108,754
Oxford City	764	£115,545
South East Oxfordshire	161	£25,437
South West Oxfordshire	506	£75,339
West Oxfordshire	246	£39,216
Undefined	*57*	*£7,961*
Total	**2,736**	**£426,025**

Figure 2 OUHFT ED Attendances (2017/2018)

13. Figure 3[10] shows 2017/18 OUHFT outpatient appointments from the identified respiratory clinics that the IRT will be able to influence. This data is from OUHFT.

Appointment Type	Clinic Resource	Appointments
New single professional Consultant appointment	Respiratory COPD New	441
Follow-up single professional Consultant appointment	Respiratory COPD FU	1,231
	Bronchiectasis FU	60
	ILD-Sarcoid FU	60
Follow-up specialist nurse appointment	Bronchiectasis FU	120
	ILD-Sarcoid FU	120
Total		**2,032**

Figure 3 OUHFT Outpatient Respiratory Appointments 2017/2018

14. Oxfordshire's approach to the provision of 'sub-acute' and community services, informed by national and international evidence and best-practice, is to organise according to the following key building blocks:
    14.1. Organising 'primary care at scale' into 18 geographical 'neighbourhoods' for a population of 30-50,000, allowing local GPs to begin to build a focus on ageing, frailty and long term condition management at neighbourhood level rather than practice level, Healthcare in neighbourhoods will be provided by integrated teams of community and primary care professionals with responsibility for identified cohorts of that neighbourhood's population (e.g. people with long-term respiratory conditions or frailty). They are based on clusters of 3-5 practices that will work together to provide an enhanced healthcare offering to their pooled patient list, so extending care beyond the traditional boundary of the individual general practice;
    14.2. Organising provision of urgent and 24x7 sub-acute and specialist advice services into three 'areas' each covering a population of 200-250,000;
    14.3. Delivering this via an emerging, integrated primary and community care organisation called 'The Oxfordshire Care Alliance' which is a joint venture between Oxford Health NHS Foundation Trust and the four federations which represent Oxfordshire GPs as provider organisations (Principal Medical Ltd, Oxfed Health and Care Ltd, Abingdon Healthcare Federation and South East Oxfordshire Federation).
    14.4. Oxford University Hospitals NHS Foundation Trust as a specialist, acute provider is essential in the provision of specialist expertise and resources to ensure effective and integrated care for frailty and long term condition management working in partnership with other providers.

Current Oxfordshire Community Respiratory Service

15. Oxfordshire CCG currently commissions an integrated Respiratory, Home Oxygen and Pulmonary Rehabilitation service from Oxford Health Foundation Trust made up of Respiratory Nurses, Respiratory Physiotherapists, Therapy Assistants and Administrators, provided in office hours 5-days a week delivering evidence based respiratory and oxygen treatments and rehabilitation. It currently provides the following aspects of care:
    15.1. In-reach into secondary care to identify and support COPD patients admitted with exacerbation of their COPD (and asthma) and identify the most advanced and complex patients who will require community follow up.
    15.2. Community management of the more complex patients referred by the hospital service and by GP's and members of the broader MDT.
    15.3. The above include optimising disease management including inhaled therapy and devices, providing self-management support and education, smoking cessation support and advice, identifying appropriate patients to attend pulmonary

rehabilitation courses and providing breathlessness management support.

15.4. Providing a pulmonary rehabilitation service – 530 attendees per year (however only if they have their own transport or can use public transport to attend).

15.5. Assessing and managing all patients requiring home oxygen therapy from hospital or community referrals.

16. However, the following added value enhancements are <u>not included</u> within the current service:

16.1. Specialist respiratory consultant clinical leadership including capacity to see patients at home

16.2. Specialist respiratory input into primary care for case discussions or MDT meetings regarding the patients who are most at risk of admission or readmission

16.3. There is no psychologist embedded in the current team and the only access is via referral or self referral to Talking Space or when patients are referred to Sobell House for palliative support.

16.4. The team are all trained as smoking cessation advisors but do not have the capacity to prescribe therapies or provide long term support due to workload, although close working with smoking cessation teams happens currently.

16.5. Pharmacist involvement

16.6. Respiratory physiotherapy input for patients in their own homes who do not have COPD but have complex respiratory needs that generalist community physiotherapists do not have the skills to deliver.

16.7. An enhanced breathless service for the more complex patients.

16.8. Formalised time to provide education to primary and secondary care colleagues to ensure all patients have consistent guideline driven input. This includes spirometry training, training around developments with inhaled therapy and device choice locally etc.

17. In addition there is a need to meet new national standards QS10[11] for quality assured spirometry for the diagnosis of COPD, and the provision of spirometry is recognised as being variable[12].

18. Patients with ILD, Sarcoidosis and bronchiectasis are looked after by hospital based specialist teams. For some patients for whom specialised expertise is not required, there is a considerable burden attending secondary care for management of their long term condition which may be addressed by provision of a community based service. This service could operate in liaison with secondary care multi-disciplinary teams (MDTs).

19. At present there is no community service to address the needs of home non-invasive ventilation (NIV) patients and neuro-muscular patients not on NIV but who are vulnerable to developing respiratory infection due to difficulties in managing airways secretions. The IRT will include respiratory physiotherapists who can help airways clearance and manage issues relating to home NIV.

Evidence for community-based specialist multi-disciplinary teams

20. OCCG seeks to implement service redesign in order to identify a cohort of patients at high risk of emergency respiratory admission, optimise their care, and improve outcomes.

21. Community-based specialist teams have been shown to dramatically reduce dependence on acute care in chronically ill patients:

21.1. Since the beginning of the King's Health Partners IRT, acute COPD admissions to King's College Hospital have reduced by 34% from 2012 to 2015. Total COPD admissions have decreased by 8% and length of stay for COPD admissions has reduced by almost one whole day[13];

	21.2. Whittington Respiratory Service - recorded prevalence of COPD increased by 22%, COPD hospital admission fell by 16%, better in-hospital mortality compared to national, significant increase in stop-smoking referral and prescription of nicotine replacement therapies and a significant increase in referrals to pulmonary rehab with a significant increase in completion rate (50% up to 92%)[14]; 21.3. Introduction of integrated respiratory service in South East Essex led to 19% reduction in COPD admissions and 24% reduction in COPD bed-days[7]; 21.4. Introduction of integrated COPD service in Salford (over 3 years) led to 25% reduction in unscheduled hospital admissions and admitted patients discharged on average 3 days earlier[7]; 21.5. An integrated service in Wessex managing high-risk respiratory patients observed a 67% reduction in acute respiratory exacerbations, a 53% reduction in unscheduled GP visits, and zero acute respiratory hospital admissions over 9-months in a cohort of 55 participants[15]; 21.6. A community integrated respiratory team in south-west Essex working with an acute medical unit identified 28% of patients admitted with COPD exacerbation were suitable for early discharge[16]; 21.7. A Canadian multidisciplinary collaborative care model with emphasis on community-based care to manage patients with idiopathic pulmonary fibrosis in their homes and support caregivers reported significantly fewer respiratory-related ER visits (p=0.002) and hospitalisations[17]. 22. Multi-disciplinary integrated care for people with COPD is recommended under NICE guidelines[18] and the NHS RightCare COPD Pathway[19]. 23. Mental health and COPD[20]: depression is associated with increased rehospitalisation rates in people with COPD and people with COPD who were not offered psychological therapies as part of their care were found to have a higher number of urgent and emergency department admissions[21].
PROJECT DEFINITION:	24. The Oxfordshire Respiratory Project Team believe the following interventions could offer a more sustainable and cost-effective strategy to reduce future non-elective admissions. 24.1. Formation of a multi-disciplinary integrated respiratory team approach (IRT) to enhance existing community and hospital-based teams by increasing consultant, nursing and physiotherapist resource and integrating with specialist GPs, a psychologist, a pharmacist, dedicated smoking-free advisor and specialist palliative care support 24.2. Identify and appropriately diagnose patients with airways disease and breathlessness from end-stage lung disease. The cohort will consist of patients who have had an emergency respiratory admission in the past year, those who are of concern to the primary care team or those who can be identified as having poorly controlled disease e.g. using inappropriate inhalers. There is potential for the IRT to identify sub-optimal care and unidentified disease and then provide effective intervention and support. 24.3. Increase accurate and timely diagnosis of respiratory disease, this will include supporting the delivery in primary care of diagnostic spirometry to approximately 1,800 patients to close the gap in reported to estimated COPD prevalence in Oxfordshire identified through Right Care.[8] 24.4. Deliver respiratory population review meetings (PRMs) and joint consultations with expert nurses and specialists within primary care settings that will focus on identification, patient review, knowledge transfer/upskilling and population health of registered population. 24.5. Optimise clinical management by focusing on high risk poorly controlled patients 24.6. Deliver a regular and established respiratory education programme to primary

	care, which includes a focus on educating healthcare professionals on promotion of self-management skills to patients 24.7. Introduce early holistic and end of life care for existing patients with advanced disease including specialist interventions for managing breathlessness 24.8. Relevant information packs and analysis will inform the work of the IRT, particularly Population Review Meetings (PRMs) within primary care. Establishment of in-practice groups for pulmonary rehabilitation and other relevant sessions such as singing and mindfulness, with a programme of effective patient education. 25. These local factors and Boehringer Ingelheim's (BI) previous experiences in this area have created a constructive environment for this joint working project. 26. It is recognised that the Oxfordshire Care Alliance – and organisation of GP practices into neighbourhoods and areas – are both emergent structural changes that will develop over time. It is therefore agreed that there may be some flexibility in the delivery of the model as these developments become more substantive. OCCG and Boehringer Ingelheim will use all reasonable endeavours to evolve the service development model to align with these changes where practicable and where this does not compromise the objectives and measurable benefits of the project. One key consideration will be the development of a 'neighbourhood' population-based approach to respiratory care in the pilot project neighbourhoods, taking into account both the prevalence of multi-morbid conditions and frailty, as well as the reality that there is only one workforce available to each neighbourhood so prioritisation decisions will need to be made. A further consideration will be the enabling and support of relevant 'area specialist teams', linked closely with Emergency Multidisciplinary Units, Minor Injury Units and Hospital at Home teams. Again, these teams care for both general frailty and multi-morbidity, so a single specialty approach needs to become embedded within the general model of care rather than creating a separate, parallel care model. This does not however mean that pathways within these care models cannot be discrete where clinically appropriate – these should be clinically led, evidence-based and designed to achieve the best care and best outcomes possible for the patient given the resources available to the neighbourhood and area team. It should be noted that provider development and testing of these emergent approaches and structural changes that relate to respiratory care will be reported and reviewed within the developing Oxfordshire health system governance structures and will not prevent the effective delivery of the IRT pilot and its objectives, or the evaluation of the pilot.
OBJECTIVES:	27. This joint working project to implement a multi-disciplinary Integrated Respiratory Team aims to: 27.1. improve access to preventative measures 27.2. increase and improve accurate, timely diagnosis 27.3. enable timely interventions to reduce ED attendances, non-elective admissions into hospital and hospital outpatient appointments 27.4. provide specialist support and in-reach into primary care 27.5. improve the patient pathway with integrated clinical governance 27.6. improve and sustain healthcare professional education 27.7. provide better patient management, including education and self-management 27.8. improve medicines optimisation and medication adherence

	27.9. integrate mental health and end of life care 27.10. Take a person-centred approach[22], as defined by National Voices' Narrative for Person-Centred Care as follows: "I can plan my care with people who work together to understand me and my carer(s), allow me control and bring together services to achieve the outcomes important to me.'
PROJECT DELIVERABLES	28. Search development and case finding in practices within the pilot project neighbourhoods, including admitted respiratory patients. 29. A pathway for referral and case management will be established that feeds in from primary care for patients identified as requiring specialist support and from secondary care for advanced, complex patients experiencing exacerbations and emergency admissions – and those patients approaching end of life. 30. Respiratory Population Review Meetings (PRMs) 31. Joint Respiratory Nurse and Practice Nurse Asthma and COPD clinics 32. Community respiratory outpatient clinics at an appropriate level 33. Domiciliary visits for assessment of house-bound patients with severe breathlessness 34. Education programmes 35. Spirometry support to enable delivery of quality standard to confirm diagnosis **Primary outcomes** 36. Reduction in emergency department (ED) attendances from 2017/18 baseline of the IRT patient cohort (defined within the background section above). The estimated achievable reduction is 20% from 2017/18 baseline. Measure: ED attendances (IRT cohort). 37. Reduction in non-elective respiratory admissions from 2017/18 baseline of the IRT patient cohort. The estimated achievable reduction is 20% from the 2017/18 baseline. Measure: non-elective inpatient admissions (IRT cohort). 38. Reduction in non-elective respiratory re-admissions within 30 days from 2017/18 baseline of the IRT patient cohort. The estimated achievable reduction is 20% from the 2017/18 baseline. Measure: non-elective inpatient re-admissions within 30 days of admission (IRT cohort). 39. Reduction or reduction in increase in all-respiratory ED attendances and non-elective admissions from the 2017/18 baseline. This outcome is to be monitored but there is no estimated achievable reduction. Measure: all-respiratory ED attendances and non-elective admissions. 40. Reduction in specified respiratory outpatient appointments from 2017/18 baseline as defined in the Background section. The estimated achievable reduction is 30% from the identified COPD clinic appointments and 10% from the Bronchiectasis and ILD-Sarcoid clinical appointments. Measure: number of outpatient appointments in the identified clinics. 41. Increase in the number of people on primary care COPD registers and a reduction in the differential between expected and observed prevalence of COPD. Measures: number of people on primary care COPD register.

42. Increase in the number of people with Respiratory Care and Support Plans in place. Baseline of OHFT record of IRT cohort care and support plans in place at commencement of pilot. Measure: OHFT record of patients (IRT cohort) with a Respiratory Care and Support Plan.

43. Improved Medicines Optimisation in IRT patient cohort group leading to prescribing in line with local formulary, quality standards and improved patient adherence over the course of the project. Measures:

    43.1. reduction in proportion of patients prescribed high dose inhaled corticosteroids (ICS) (measured by epact2 data)

    43.2. reduction in proportion of patients receiving 5 or fewer ICS products in a 12 month period indicating greater adherence (measured by epact2 data)

    43.3. reduction in proportion of patients receiving 6 or more short acting beta agonist inhalers in a 12 month period indicating reduction of symptoms (measured by epact2 data)

    43.4. increase in use of formulary choice inhalers and reduction in primary care respiratory medicines spend (measured by epact2 data and practice level audits of interventions made as part of the IRT)

    43.5. Patient feedback measures, which would be baselined in the early stages of the project and then evaluated against this baseline

Secondary outcomes

44. Improvement in smoking cessation as measured by 4 week quit rate of those referred to smoking cessation services by IRT. Measure: Stop Smoking Service referrals (from IRT) and 4 week quits from that cohort.

45. Increase in the number of patients recognised as needing end of life supportive care and having advance care plans in place. Measure: proportion of IRT cohort identified as end of life, placed on primary care palliative register (primary care) with a digital Proactive Care Plan in place.

46. Improved recognition of mental health problems and improved mental health outcomes. Measure: proportion of IRT cohort identified as having a mental health condition and improvement in mental wellbeing through GAD7[23] anxiety measure, the PHQ9[24] depressions measure and the Work and Social Adjustment Scale[25] to measure impact on daily living

47. Improvement in patient quality of life. Measure: condition specific quality of life measures (HRQoL) and/or EQ-5D-5L[26].

48. Improvement in breathlessness score in patients with severe breathlessness seen by IRT. Measure: visual analogue score.

49. Uptake of pulmonary rehabilitation and reduction in waiting time. Measure: Pulmonary rehabilitation attendance and waiting time for IRT cohort

50. Staff /stakeholder feedback from neighbourhood and area teams

SCOPE:

51. Project will implement an enhanced multi-disciplinary integrated respiratory team (IRT). The staff for the IRT will be employed by existing Oxfordshire health care providers.

52. The pilot of IRT will work in neighbourhoods in Oxford City and part of the North Oxfordshire area and will be applicable to those patients registered to GP practices within those neighbourhoods. The IRT will operate in both geographies from the start to the end of the project. Figure 4 is a table of practices and the defined areas and neighbourhoods they are within, which defines the scope of the registered population that the IRT will cover during the pilot.

Practice name	Area	Neighbourhood
Banbury Health Centre	North	Banbury
Cropredy Surgery	North	Banbury
Hightown Surgery	North	Banbury
Horsefair Surgery	North	Banbury
West Bar Surgery	North	Banbury
Windrush Surgery (Banbury)	North	Banbury
Woodlands Surgery	North	Banbury
Bloxham Surgery	North	North Rural
Chipping Norton Health Centre	North	North Rural
Deddington Health Centre	North	North Rural
Sibford Gower Surgery	North	North Rural
Wychwood Surgery	North	North Rural
Beaumont St (19)	Oxford City	Central and South West Oxford
Beaumont St (27)	Oxford City	Central and South West Oxford
Beaumont St (28)	Oxford City	Central and South West Oxford
Botley Medical Centre	Oxford City	Central and South West Oxford
Kennington Health Centre	Oxford City	Central and South West Oxford
King Edward Street	Oxford City	Central and South West Oxford
Luther Street Medical Centre	Oxford City	
South Oxford Health Centre	Oxford City	Central and South West Oxford
Bartlemas Surgery	Oxford City	East Oxford
Cowley Road Medical Practice	Oxford City	East Oxford
St Bartholomews MC	Oxford City	East Oxford
St Clements Surgery	Oxford City	East Oxford
Hedena Health	Oxford City	Headington
Manor Surgery Headington	Oxford City	Headington
Banbury Road (172)	Oxford City	North Oxford
Jericho Health Centre (Leaver)	Oxford City	North Oxford
Observatory Medical Practice	Oxford City	North Oxford
Summertown Health Centre	Oxford City	North Oxford
Donnington HC	Oxford City	South East Oxford
Hollow Way Medical Centre	Oxford City	South East Oxford

Temple Cowley Health Centre	Oxford City	South East Oxford
The Leys Health Centre	Oxford City	South East Oxford

Figure 4 General Practice defined Neighbourhoods

Project duration: 15 months.

Project Start Date: 1 November 2018

Project End Date: 30 January 2020

56. The IRT will specifically provide enhanced elements of care and new pathways beyond that currently provided by the existing respiratory services in Oxfordshire. This is described in more detail below. However the IRT will need to operate and interface seamlessly with currently commissioned respiratory services, in particular the current Community Respiratory Service.

57. The patients within the remit of the IRT will include diagnosed and undiagnosed patients with the following:

57.1. Patients with airways disease: Asthma and COPD
57.2. Bronchiectasis patients not requiring intensive secondary care management
57.3. End-stage Interstitial lung disease patients including those with sarcoidosis
57.4. Patients with neuromuscular disease or on home NIV requiring physiotherapy input to optimise airways clearance and manage home NIV

58. Monitoring and evaluation will be conducted throughout the duration of the project and reported into the Joint Project Board. Key evaluation points will be at 6 months and 12 months in the project timeline. An interim evaluation will be at 6 months and full evaluation will take place after 12 months of operation. A full evaluation report on the project will be produced after 12 months of operation.

59. The project will require joint contribution in staff resource and funding from both OCCG and BI to enable successful mobilisation, delivery and evaluation. It will also require project and operational management support from the provider organisations to support the healthcare professionals in delivering the service.

CONSTRAINTS:

60. ABPI Code of Practice for the Pharmaceutical Industry 2016[27], particularly Clause 20 (set out in full in Appendix A).

61. UK Law

62. Oxfordshire CCG policies and governance, particularly the Joint Working and Sponsorship Arrangements with Commercial Organisations (including the Pharmaceutical Industry) Policy[28].

63. Data Protection Act / GDPR

64. The project will need to operate within the geographical limits set out in the scope and the financial controls of the budget. It will also need to adhere to the project governance framework set out in Appendix B.

ACCEPTANCE CRITERIA:	65. Both parties will need to contribute comparable resources (Financial, skill, time, personnel). 65.1. BI will contribute a portion of the following staffing resource to the project: BI Project Manager, BI Epidemiologist, BI Value Outcomes Consultant, BI Medical Writer, Pharmaceutical physician 65.2. BI will also contribute funding to the operation of the IRT including staffing as set out in the IRT Project Costs spreadsheet (separate document). The total BI funding contribution is set out in the 'Business Case' section below. 65.3. OCCG will contribute a portion of the following staffing resource to the project: Commissioning Manager, Assistant Project Manager, Clinical Lead for Long Term Conditions, City Deputy Locality Clinical Director, Communication Officer and CSU Analyst. 65.4. OCCG will contribute specific funding as set out in the IRT Project Costs spreadsheet. The total OCCG contribution is set out in the 'Business Case' section below. 65.5. OCCG will also contribute elements of resource from currently commissioned IAPT and Community Respiratory services which will be fundamentally integral to the operation of the IRT. 66. The project evaluation will be underpinned by the collection of health care data to be specified. 67. The IRT need to be sustainable and replicable going forward following the pilot. The project will seek to establish if the operation of the IRT delivers the project objectives and is a viable health care intervention to be commissioned by OCCG on a substantive basis going forward and also delivered county-wide. If successful it should inform the future commissioning of the community-based respiratory services in entirety. 68. Must be able to report and share findings through case studies for write up of project. The case studies will provide overviews of the project purpose, approach and achievements. This will include reporting on health outcomes achieved. 69. Must be designed to demonstrate improvements in treatment and outcomes for patients and cost efficiencies through reduction in hospitalisations and treatment costs.
PROJECT APPROACH:	70. Development and implementation of a multi-disciplinary integrated respiratory team (IRT) to deliver a 5 day/week pilot service split across the two geographies , building on the existing community respiratory and home oxygen nursing team, and pulmonary rehabilitation programme, and aligning closely with neighbourhood and area resources including: 70.1. Specialist respiratory consultant leadership of the IRT with clinical input, including contribution to patient home visits where required 70.2. Respiratory GPs with joint responsibility for triage of incoming referrals to the IRT with nurses and clinical input including contribution to patient home visits. 70.3. A revised community respiratory nursing structure to contribute to the overall leadership of the IRT and to enable enhanced in-reach into primary care to

reduce hospital admissions, building on existing in-reach into acute care.

70.4. The leadership team of the IRT will consist of the specialist respiratory consultant, respiratory GP and lead specialist respiratory nurse.

70.5. Respiratory physiotherapists to assist in providing support to respiratory and neuromuscular patients at increased risk of pneumonias and hospitalisations by providing specialist respiratory physiotherapy input and training for carers and other community staff to ensure adequate secretion clearance. They will educate and support general community physiotherapists who are in contact with these patients to upskill them and provide direct support. They will also target patients that struggle to attend pulmonary rehabilitation courses and provide anxiety management, low level exercise, medication control, pacing strategies with the aim to decrease GP contact, hospital admissions, 999 calls - this could be provided in GP practices, neighbourhood settings and patients' homes. Finally they will research the group of patients who do not attend pulmonary rehabilitation to enable further understanding and ways to restructure the service.

70.6. IAPT Psychological input to help patients manage depression, anxiety and breathlessness.

70.7. Sign-posting to relevant patient groups such as singing, 'breathe-easy', mind/body/breath integration, exercise (e.g. Generation Games). A patient representative will be included on the Project Implementation Group to establish reliable means to link into relevant patient groups and relevant third sector bodies.

70.8. Clinical pharmacist to support strategic medicines management analysis and advice as well as appropriate prescription switching and inhaler selection working with practices and the Clinical Pharmacists already operating in practices and neighbourhoods. .

70.9. Smoke-Free advisor/coordinator – remit to promote smoking cessation, streamlining take-up of smoking cessation advice and ensuring smoke-free environments. Skilled in motivational and behaviour change to get long-term smokers to quit.

70.10. Palliative care practitioner

70.11. Lung function technician

70.12. Other representatives of neighbourhood and area teams to be represented as required in operational meetings.

71. A pathway of referral and case management to the IRT will be established that feeds in from practices and neighbourhoods for patients identified as requiring specialist support and from secondary care for advanced, complex patients experiencing exacerbations and emergency admissions and those patients approaching end of life. Reporting processes to be established which ensure the IRT has sight of all respiratory emergency admissions into acute care with a plan of review and diagnosis.

72. The IRT would coordinate patient-centred care and support planning for the patient jointly with the defined neighbourhood and area team. This could include a home visit

and assessment to determine the impact of their home as an environmental factor impacting their respiratory condition, and if so, relevant contact would be made with council services. It would also include planned physiotherapy, palliative care input, smoking cessation, and psychological support where required. Where appropriate this will include liaison with the local Emergency Multidisciplinary Unit, Hospital at Home team and neighbourhood primary/community care team.

73. The IRT would support patients with severe breathlessness due to end-stage lung disease in ways they can effectively manage their breathlessness at home without requiring admission. This will require delivery of multi-professional input including specialist palliative skills.

Key elements of the enhanced IRT:

74. **Population Review Meetings (PRMs)**

The IRT would deliver targeted case discussion and virtual clinics/ PRMs in primary care with the dual purpose of managing complex patients closer to home and educating/upskilling primary care and neighbourhood team professionals. This would include pharmacist input to ensure inhaled medicines optimisation and adherence. 34 practices in the City and North localities in Oxfordshire will have access to at least one 2-hour PRM every 6 months including Consultant, GP and specialist nurse input. The specific arrangements for IRT PRM meetings and other routine communications and information sharing will be coordinated with neighbourhood and area PRMs. The administrative and IT infrastructure will be organised in such a way as to optimise local resources and interface with other neighbourhood work.

75. **Healthcare Professional Education**

The IRT would develop an education programme to support practice, neighbourhood and area teams to deliver respiratory disease diagnosis and management and appropriate inhaler selection, with effective patient tuition/support about inhaler technique. Members of the IRT would deliver the education programme which would consist of meetings including a mixture of lectures and practical hands on sessions. Educational strategy would support spirometry accreditation at neighbourhood and wider areas as appropriate.

76. **Diagnosis**

IRT to provide oversight of diagnostic spirometry potentially delivered on a GP neighbourhood level or wider areas as appropriate (via spirometry hubs) and provide spirometry up-skilling where required. This has the potential to reduce referrals into secondary care outpatients by reducing misdiagnosis. Earlier and appropriate diagnosis will enable care and management in the community.

77. **Smoking status and support**

Patients will be given a Carbon Monoxide (CO) test, regardless of declared smoking status. Those patients who are smokers will be offered an “opt out” referral to stop smoking behaviour support and associated pharmacotherapy. If the reading indicates smoking or living with a smoker, in the first instance they will be referred to a stop smoking advisor.

This advisor will be particularly experienced and trained in helping patients with a long term

condition who continue to smoke. They will deliver evidenced based, NCSCT behavioural support in-line with NICE guidance NG92[29]. They will provide a flexible approach primarily through face to face sessions. Support will also be available through other means, such as Skype or other similar platform, phone calls, texts and e-mails, letters. Regular follow up contact and motivation for 12 months.

The advisor will have the appropriate resource to develop and remain highly skilled in behavioural science. They will also have capacity to develop and deliver approaches and interventions to specific segments of the cohort.

Where the patient is living with a smoker, they will be proactively encouraged to ideally quit, using an opt out referral to Local Stop Smoking Services (or where appropriate, e.g. have conditions themselves and capacity allows the IRT Smoking Advisor) or advice and follow up on creating smoke-free environments, particularly in the family home and car.

78. **Physical and mental wellbeing**

An IRT member will promote and refer to community based interventions that support the physical and mental wellbeing of patients. They will have appropriate time available to liaise and network with partners in the community who can support respiratory patients with appropriate community based interventions such as gentle exercise, singing/spoken word and other interventions which have some evidence to show positive effect on the health and wellbeing of the patient, or at the very least are unknown to cause harm. For example, use the local online Livewell database (https://livewell.oxfordshire.gov.uk/).

79. **Home environment**

All the members of the IRT will have capacity/time available to attend training about the impacts of poor quality housing (cold and damp, in particular) in people's homes to ensure that they provide a comprehensive assessment to reduce the likelihood of emergency or unplanned admissions brought on by cold and/or damp homes. It is proposed two hours, once a year, perhaps in two one hour sessions. These sessions can be provided by existing partnerships active in the County, e.g. Better Housing Better Health. (a total of 1 day a year)

An appropriate member of the IRT team will develop active partnerships to support effective referral pathways into these services e.g. making sure the questions are asked, data capture, referrals (not signposting) and appropriate follow up to facilitate the outcomes of that referral. Also time to support data collection/transfer to partners to demonstrate effectiveness of these services on reducing unplanned and emergency conditions.

80. **Air Quality**

In order to reduce the impact of poor (outdoor) air quality, an appropriate IRT member will have appropriate time available to identify and refer patients who are living in Air Quality Management Areas (AQMAs) or near busy roads into the appropriate officer in the District Council. These patients will receive additional information about the impact of poor air quality on their condition and a plan developed to manage the impact of incidences of high levels of poor air quality from the appropriate IRT member.

An initial project plan will be submitted as part of the acceptance of the Project Initiation Document and will include

- Work breakdown structure of key deliverables
- A high-level timeline of deliverables

INTERFACES:

81. The project will interface with the following services:

81.1. Oxfordshire University Hospitals NHS Foundation Trust;
81.2. Oxford Health NHS Foundation Trust
81.3. NHS Oxfordshire CCG member practices
81.4. Oxfordshire GP Federations
81.5. Oxfordshire Care Alliance – Integrated Frailty Service
81.6. Oxfordshire County Council Public Health commissioned services
81.7. Other community and voluntary sector organisations and providers
81.8. 3rd party providers for data gathering & case management i.e. CSU/EMIS/Cerner

ASSUMPTIONS:

82. The following are key assumptions in this project:

82.1. The burden of long term disease is accurately described in this document and the supporting references used;
82.2. The RightCare[8], other data sources and references correctly identify key areas of improvement for Oxfordshire CCG;
82.3. That the approach to identifying emerging risk patients is possible, and that providing these patients with IRT interventions will improve outcomes;
82.4. Primary care data and acute sector data can be accessed;
82.5. Costs during the pilot period will reference standard NHS agreements such as Agenda for Change pay scales; and
82.6. External factors, including issues like Brexit or changes in NHS policy, will have a negligible impact of this project.

BUSINESS CASE:

83. **IRT pilot costs**

83.1. *IRT costs by BI financial year(Jan-Dec)*

	Total Cost	**2018**	**2019**	**2020**
Staffing	£726,611	£89,693	£586,081	£50,837
Staffing overheads (20%)	£145,322	£17,939	£117,216	£10,167
Travel, Equipment & Consumables	£20,938	£2,792	£16,750	£1,396
PRMs	£26,705	£3,561	£21,364	£1,780
Diagnostic spirometry	£9,696	£1,293	£7,757	£646
IRT Operational Total	**£929,272**	**£115,277**	**£749,169**	**£64,827**
	Total Cost	**2018**	**2019**	**2020**
BI Funding (to IRT Operational)	£747,549	£92,484	£602,831	£52,233
OCCG New Spend Contribution (to IRT Operational excl. IAPT And Community Respiratory Service)	£181,724	£22,792	£146,337	£12,594

OCCG Contribution (to IRT Project incl. new spend (above) and current staff and currently commissioned services)	*£908,724*	*£126,914*	*£723,145*	*£58,665*
IRT Project Total	**£1,656,272**	**£219,399**	**£1,325,976**	**£110,897**

83.2. *IRT costs and payments by project phase*

	Project Phase 1 Transfer (Nov 2018-Apr 2019)	**Project Phase 2 Transfer (May-Oct 2019)**	**Project Phase 3 Transfer (Nov 2019-Jan 2020)**
BI Funding (to IRT Operational)	£277,453	£313,397	£156,698
OCCG New Spend Contribution (to IRT Operational excl. IAPT And Community Respiratory Service)	£68,376	£75,565	£37,782
IRT Project Total	**£345,829**	**£388,962**	**£194,481**

84. **Estimated activity and cost savings**

84.1. *Estimated gross IRT pilot savings from Oxford City and North Oxfordshire localities from 2017/18 baseline.*

The estimated saving is based on the annual (12 month) saving from 2017/18 baseline being achieved over the 15 months of the pilot. The ED attendance and non-elective (NEL) admissions data has been provided by South Central and West Commissioning Support Unit (SCW CSU) from Secondary Uses Service (SUS) data, and the activity baseline has been discussed and agreed with an OUHFT Respiratory Consultant and estimated activity saving has been discussed and agreed with the IRT Clinical and Prevention working group of healthcare professionals, including the OUHFT Consultant. The outpatients baseline and estimated saving is based on specific clinics identified by the OUHFT Respiratory service that can be influenced by the IRT, this baseline and estimated saving has then been proportionately projected for the City and North localities based on the COPD register. The estimated prescribing saving is based on medicines optimisation through IRT informed by the OCCG Medicines Optimisation Team.

Activity Type	**City and North localities - activity and cost baseline (2017/18)**	**City and North localities - Estimated IRT Pilot Saving (1 Nov 2018 - 31 Jan 2020)**
ED Attendances (activity)	1,429	286
ED Attendances (cost)	£224,299	£44,860
NEL Admissions (activity)	2,391	478
NEL Admissions (cost)	£5,275,235	£1,055,047

Outpatient appointments (activity)	767	215
Outpatient appointments (cost)	£102,949	£29,180
Prescribing (cost)		£74,070
Total (Gross) Saving		**£1,203,156**
OCCG Net Saving (including OCCG New Spend only)		£1,021,433
OCCG Net Saving (including full IRT Operational Cost - if OCCG were covering the total cost of the pilot)		£273,884

84.2. *Estimated IRT annual saving if fully operational across Oxfordshire (post-pilot)*

Activity Type	**Activity saved**	**Cost saved**
ED Attendances	547	£85,205
NEL Admissions	1035	£2,454,034
Outpatient appointments	520	£70,419
Prescribing		£143,000
Total Saving (annual)		**£2,752,658**

Average length of stay for an NEL admission of the IRT cohort is 5 bed days. Bed days saved from the above annual NEL admissions saved is estimated at 5,234 bed days.

IRT Operational Cost (annual)	£1,416,002
Gross saving from IRT (annual)	£2,752,658
Net saving from IRT (annual)	**£1,336,656**

This illustrates the potential sustainability of the IRT beyond the pilot if estimated outcomes and savings are achieved.

PROJECT ORGANISATIONAL STRUCTURE:

85. **IRT Joint Project Board**

- Membership: 3 voting members from OCCG and 3 voting members from BI. With agreement of voting Board members, additional non-voting members of the Board may be invited to attend Board meetings.
- Purpose: Responsible for strategic decision-making on the project including key gateway decision points regarding, evaluation, project exit and wider rollout within the project duration. This will include the management of joint project funding and resources from OCCG and BI and decision-making over the release of funding. The Joint Project Board will receive regular reports from the

	IRT Project Implementation Group/Project Manager to assess the progress and effectiveness of the pilot IRT. • Accountability: The Joint Project Board will be accountable to the OCCG Board via the OCCG Executive committee and the BI Human Pharma Leadership Team (HPLT) for the progress and effectiveness of the IRT pilot. • Given its importance to secondary care activity this project will also be reported into other appropriate system forums. • See full IRT Governance Framework in **Appendix B**.
STAKEHOLDERS:	86. Benefits to Stakeholders: 86.1. **Patients** • Improved quality of life • Care closer to home • Earlier and accurate diagnosis • Holistic, multi-disciplinary care planning • Support to enable better self-care and resilience • Psychological support to manage breathlessness anxiety and exacerbations • Proactive medicines optimisation • Facilitated access to preventative measures 86.2. **NHS Oxfordshire CCG** & other Care Organisations • Reduced ED attendances, non-elective admissions and re-admissions – thereby reducing pressure on A&E and inpatient capacity • Increased support to patients around hospital discharge with reduction in time spent in hospital • Increased provision of outpatient appointments by hospital teams nearer to patients' homes • Better coordinated and integrated care with less delay and hand offs • Integration of physical and mental health • Proactive and preventative approach reducing system costs overall • Optimised clinical management and prescribing 86.3. **Boehringer Ingelheim Limited** • Improved understanding of the challenges and support needed to implement an integrated multi-disciplinary care pathway. • Recognition as a trusted partner for Joint Working projects with the NHS. • Ability to take and share the learning from this project to other regions in the UK to support improved patient care. • More appropriate use of medicines for patients with respiratory diseases, some of which may be Boehringer Ingelheim medicines.
PROJECT EXECUTIVE / SPONSOR:	87. From NHS Oxfordshire CCG: Chief Operating Officer, OCCG From Boehringer Ingelheim UK & Ireland: Medical Director, BIL

PROJECT MANAGER:	88. Boehringer Ingelheim has appointed a PIO Project Manager. Their time associated with the project forms part of the BI contribution. The OCCG have also appointed a Commissioning Manager for Long Term Conditions and End of Life Care.
PROJECT TEAM:	89. The Project Implementation Group will be the group that leads the delivery of the project. The Commissioning Manager for Long Term Conditions and End of Life Care and the PIO Project Manager will provide project management for the project overall, with relevant provider organisation managers/project managers providing operational management and support. The Project Implementation Group will report into the Joint Project Board. The Project Implementation Group will include: Oxfordshire CCG: • Head of Planned Care and Long Term Conditions • Commissioning Manager for Long Term Conditions and End of Life Care • Clinical Lead for Long Term Conditions • Deputy Clinical Director, Oxford City Locality • Medicines Optimisation Pharmacist Oxford University Hospitals NHS Foundation Trust: • Respiratory Consultant • Operational Services Manager Oxford Health NHS Foundation Trust: • Head of Community Services • Head of Urgent Care • Senior Interface GP • Specialist Respiratory Nurse • Allied Health Professional Lead • Operational Manager • Respiratory Physiotherapist • Clinical Psychologist Principal Medical Ltd • To be determined. Oxfed Health and Care Ltd • To be determined. Oxfordshire County Council – Public Health: • Health Improvement Practitioner Boehringer Ingelheim including: • Medical Affairs Manager • PIO Project Manager • Market Access Editor • Values Outcomes Consultant The IRT Project Implementation Group will include at least one patient who is an expert by experience and establish reliable means to link into relevant patient groups and relevant third sector bodies.

	Members of the Project Implementation Group may change depending on organisations' changes in personnel or structures.
QUALITY:	90. The project will adhere to the relevant NICE guidance documents such as the technology appraisals, clinical guidelines, quality standards, key therapeutics topics and evidence summaries in relevant disease areas. 91. An OCCG Quality Impact Assessment will be carried out on the project.
PROJECT PLAN:	The project plan is detailed in **Appendix C**.
EXIT	92. As set out in the governance framework, the Joint Project Board will consist of 3 voting members from OCCG and 3 voting members from BI. The Joint Project Board's decisions will be final and will be made by the plurality of votes. At all times the Board will work to constructive partnership and consensus based decision making. 93. OCCG and BI recognise the unique and complex nature of this project within the Oxfordshire healthcare system. It is also recognised that this 15 month project is a pilot to test this model of care. OCCG and BI recognise the importance of joint working and funding being maintained throughout the project to enable project success and to avoid negative impact for patients across the localities as well as organisational, reputational and financial damage for either party. 94. Therefore it is recognised that exit from the project can only be exercised: 94.1. By agreement of both parties 94.2. Upon complete breakdown of the relationship between OCCG and BI or 94.3. In the event that BI is excluded from taking an active role on the project (as is a requirement of joint working) 95. However, the joint working arrangement shall be dissolved at any time if any party wishes to withdraw; a notice period will be given of 3 months • Any outstanding matters must be wound up by all parties by agreement. • If BI decides to terminate this Joint Working Agreement, BI shall compensate OCCG for the amounts already committed under the Joint Working Agreement up to the date when the termination notice was served. • Moreover, each Party shall equally contribute to the salary of personnel employed to deliver enhanced IRT services up to a maximum of three month notice period. • Termination of the joint working arrangement under this clause is the only remedy available to the Parties for any breaches of their obligation hereunder. 96. The Joint Project Board will work together to identify and mitigate risks to the project

	throughout the duration of the project. Joint meetings will have minutes documented and shared within 7 days of each meeting.
PROJECT CONTROLS:	97. Before the project is progressed the Joint Project Board, comprising key stakeholders from Oxfordshire CCG and BI, will be established. All parties must sign an agreed Terms of Reference (Appendix B) for the Joint Project Board and a Joint Working Agreement (JWA) contract must be agreed and signed between Oxfordshire CCG and BI. All decisions on the project need to be agreed by the Joint Project Board and where appropriate ratified by the Oxfordshire CCG Board or Executive, with the expectation of the following: 98. The outcomes of this work will be documented. These outcomes will (A) be continuously monitored to ensure there is a benefit to the target patients, and (B) documented in an evaluation report of the project that will be collaboratively produced by Oxfordshire CCG and BI. The Joint Project Board will seek to appoint an independent 3rd party(ies) to advise on the evaluation of the pilot. 99. For the conditions targeted by this project there are multiple pharmaceutical and non-pharmaceutical treatment options available. 100. Any medicines used will be dependent on the agreed Oxfordshire Medicines Formulary. 101. No use of BI's medicines is implied or required within the scope of this project. Improved diagnosis and management of the conditions outlined may result in increased and earlier use of appropriate medications, some of which may be BI medicines. However, this is not the reason for the design of this project and there is and will be no influence placed on IRT staff to use BI medicines. 102. The joint working relationship between Oxfordshire CCG and BI, the project, analysis, outcomes and learning is to have reference to: 102.1. Clause 20 of the ABPI Code of Practice[27] for the Pharmaceutical Industry (set out in full at Appendix A), and; 102.2. Department of Health/ABPI - Moving beyond sponsorship: Interactive toolkit for joint working between the NHS and the pharmaceutical industry[30] 102.3. NHS Oxfordshire Clinical Commissioning Group's Joint Working and Sponsorship Arrangements with Commercial Organisations (including the Pharmaceutical Industry) Policy[28] 103. All materials that are to be shared outside the Joint Project Board and Project Implementation Group will be subject to approval/certification to ensure compliance with the ABPI code of practice. Clause 14.3 of the ABPI Code of Practice states: The following must be certified in advance in a manner similar to that provided for by Clause 14.1: • educational material for the public or patients issued by companies which relates to diseases or medicines but is not intended as promotion for those medicines • material relating to working with patient organisations as described in

Clause 27 and its supplementary information

- material relating to joint working between the NHS and the pharmaceutical industry as described in Clause 20 and its supplementary information
- material relating to patient support programmes involving the provision to health professionals of items to be passed on to patients as described in Clause 18.2 and its supplementary information
- non-promotional material for patients or health professionals relating to the provision of medical and educational goods and services, including relevant internal company instructions, as described in Clause 19.1 and paragraph 8 of its supplementary information.

104. In line with Clause 20 of the ABPI, joint working between the pharmaceutical industry and the NHS must be conducted in an open and transparent manner. Therefore, materials and communications developed from the project will need to include the following wording:

*This **material/poster/educational programme** has been produced as part of a joint working partnership between NHS Oxfordshire CCG and Boehringer Ingelheim Ltd.*

Consideration will be given to using both party logos where appropriate. This requirement will cease at the end of the project.

105. OCCG will use the joint project funding to commission the local NHS healthcare providers to deliver the IRT workforce, interventions, outputs and outcomes for the period of the project. OCCG and local NHS healthcare providers will provide all clinical care and support and take full responsibility for clinical decision-making. BI will not employ any IRT operational staff. Only non-promotional BI staff will be involved in the project and will have no influence over the clinical and prescribing decision-making of the IRT staff. Any BI promotional staff engaging with providers or clinicians in Oxfordshire, will not use the project to gain access or favour within Oxfordshire;

106. Ownership of the data and information generated as part of the project will rest with the relevant NHS organisations involved as Data Controllers. BI will have no access to patient identifiable or pseudonymised data, only fully anonymised and aggregated data will be shared with BI in the course of the project and its evaluation. Any sharing of data with BI will be governed by UK data protection law, OCCG's information governance framework and a Data Sharing Agreement agreed and signed between OCCG and BI;

107. All intellectual property from the project (including all developments and materials) and its evaluation will be freely shared in the public domain and will be free for the NHS to use;

108. BI agrees to signpost other NHS organisations to OCCG regarding the development and operation of the IRT. Oxfordshire CCG agrees to be a reference site for future BI partnership projects.

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Appendix A: ABPI Code of Practice 2016 Clause 20 – Joint Working

Joint working between one or more pharmaceutical companies and the NHS and others is acceptable provided that this is carried out in a manner compatible with the Code. Joint working must always benefit patients.

A formal written agreement must be in place and an executive summary of the joint working agreement must be made publicly available before arrangements are implemented.

Transfers of value made by companies in connection with joint working must be publicly disclosed.

Clause 20 Joint Working

The Department of Health defines joint working between the NHS and the pharmaceutical industry as situations where, for the benefit of patients, one or more pharmaceutical companies and the NHS pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery.

Each party must make a significant contribution and the outcomes must be measured. Treatments must be in line with nationally accepted clinical guidance where such exists. Joint working between the pharmaceutical industry and the NHS must be conducted in an open and transparent manner. Joint working must be for the benefit of patients but it is expected that the arrangements will also benefit the NHS and the pharmaceutical company or companies involved. Joint working differs from the situation where pharmaceutical companies simply provide funds for a specific event or programme.

The Department of Health has issued Best practice guidance on joint working between the NHS and pharmaceutical industry and other relevant commercial organisations. The Department of Health and the ABPI have jointly issued Moving beyond sponsorship: interactive toolkit for joint working between the NHS and the pharmaceutical industry.

The ABPI has produced guidance notes on joint working between pharmaceutical companies and the NHS and others for the benefit of patients. The ABPI Guidance refers to the requirements of the Code but goes well beyond them.

When considering joint working, companies should take account of the guidance which has been issued by the ABPI and the Department of Health. Joint working is acceptable in principle provided that it is carried out in conformity with the Code. In particular, it must not constitute an inducement to health professionals or other relevant decision makers to prescribe, supply, recommend, buy or sell any medicine. It must therefore always be ensured that any and all of the benefits of joint working which are due to the NHS, go not to individuals or practices but to an NHS or other organisation.

A joint working agreement can be based on the use of a particular medicine of a company party to the agreement, but only if the requirements below are complied with and only if the parties have satisfied themselves that the use of the medicine will enhance patient care. Goods and services provided by the company as part of the joint working agreement must be relevant to the medicines involved and the agreement as a whole must be fair and reasonable. Any goods and services provided by the company must themselves contribute to patient care.

The written agreement must cover the following points:

- the name of the joint working project, the parties to the agreement, the date and the term of the agreement
- the expected benefits for patients, the NHS and the pharmaceutical company; patient benefits should always be stated first and patient outcomes should be measured
- an outline of the financial arrangements
- the roles and responsibilities of the NHS and the pharmaceutical company and how the success of the project will be measured, when and by whom; all aspects of input should be included
- the planned publication of any data or outcomes
- if a pharmaceutical company enters into a joint working agreement on the basis that its product is already included in an appropriate place on the local formulary, a clear reference to

this should be included in the joint working agreement so that all the parties are clear as to what has been agreed

- contingency arrangements to cover possible unforeseen circumstances such as changes to summaries of product characteristics and updated clinical guidance; agreements should include a dispute resolution clause and disengagement/exit criteria including an acknowledgement by the parties that the project might need to be amended or stopped if a breach of the Code is ruled
- publication by the company of an executive summary of the joint working agreement, for example on a clearly defined website or section of a website, such as on the company's or companies' website; the NHS organisation should also be encouraged to publish this.

The requirement to make the executive summary public applies to joint working projects started on or after 1 May 2011 or ongoing on that date.

Attention is drawn to the certification requirements set out in Clause 14.3 which apply to material relating to joint working including the project initiation documentation and the executive summary of the joint working agreement. Only the final documents etc for any joint working project need be certified. All documents etc used during the development of the project should be of the same standard as certified material but there is no requirement to certify such materials. The joint working agreement does not need to be certified.

Clause 19.2 is relevant to a joint working agreement between a pharmaceutical company and the NHS which does not involve the use and purchase of any of the company's medicines.

Although the ABPI Guidance is aimed principally at joint working between pharmaceutical companies and the NHS, it also covers joint working conducted though third party service providers and/or with suppliers of private healthcare.

More detail as to the requirements for joint working is provided in the ABPI Guidance which should be consulted when joint working is contemplated.

Joint working should be distinguished from straightforward sales where medicines are simply sold and there are no accompanying goods and services etc and from package deals and outcome or risk sharing agreements as defined in the supplementary information to Clause 18.1.

Clause 20 Disclosure

The information required by Clause 20 as to transfers of value must be publicly disclosed in relation to transfers of value made in 2015 and each calendar year thereafter, giving in each case the financial amount or value and the name of the recipient.

Companies must ensure that the amount spent on joint working projects is made public irrespective of whether the value is transferred to a healthcare organisation or some other funding model is used.

Disclosure must be carried out in accordance with Clause 24.

Appendix B: Integrated Respiratory Team Project – Governance Framework

This document sets out the governance framework for the pilot of an Integrated Respiratory Team (IRT) in Oxfordshire enabled through a joint working agreement between Oxfordshire Clinical Commissioning Group (OCCG) and Boehringer Ingelheim Ltd (BI). The operational delivery of the IRT pilot will be delivered by Oxfordshire health care providers: Oxford University Hospitals NHS Foundation Trust (OUHFT), Oxford Health Foundation Trust (OHFT), GP Federations and the Oxfordshire County Council (OCC) commissioned stop smoking provider, Solutions 4 Health Ltd (S4HL). This project will be 15 months in duration, commencing on 1 November 2018 and ending on 30 January 2020. A decision to substantively commission the IRT in whole or in part following the end of the pilot remains the sole responsibility of OCCG.

IRT Joint Project Board

- Membership: 3 voting members from OCCG and 3 voting members from BI. With agreement of voting Board members, additional non-voting members of the Board may be invited to attend Board meetings.

- Purpose: Responsible for strategic decision-making on the project including key gateway decision points regarding, evaluation, project exit and wider rollout within the project duration. This will include the management of joint project funding and resources from OCCG and BI and decision-making over the release of funding. The Joint Project Board will receive regular reports from the IRT Project Implementation Group/Project Manager to assess the progress and effectiveness of the pilot IRT.

- Accountability: The Joint Project Board will be accountable to the OCCG Board via the OCCG Executive committee and the BI Human Pharma Leadership Team (HPLT) for the progress and effectiveness of the IRT pilot.

- Given its importance to secondary care activity this project will also be reported into other appropriate system forums.

Terms of Reference

The Joint Project Board will be the accountable body for the effective planning and implementation of the IRT project such that it results in outcomes that benefit patients, OCCG and BI.

The Board will ensure that the following are clearly identified and agreed:

- The vision, objectives and outcomes of the project
- Deliverables and key success factors
- Timelines and milestones
- Accountabilities, roles and responsibilities
- Governance arrangements
- Arrangements for monitoring and evaluation
- An exit strategy.

It will ensure transparency and probity in the conduct of the project, compliance with Department of Health Guidance, professional and NHS standards of business conduct, and the ABPI Code of Practice. It will draw up a joint working agreement on behalf of the parties.

It will be accountable for the development, sign-off, delivery and communication of all formal documentation necessary for the effective running of the project, including:

- A Project Initiation Document
- Risk assessment

- Business case
- Detailed project plan, including management of and communication with stakeholders

It will be accountable for management of budgets and use of other resources.

It will put appropriate monitoring and evaluation processes in place and monitor progress against objectives, milestones, deliverables, and the project plan, with responsibility for anticipating, highlighting and resolving challenges to delivery of the plan.

In reviewing progress, it will make decisions on revisions to the arrangements as and when necessary. It will also recommend continuation or termination of the project, including in the case of the former, what appropriate structures and mechanisms will be needed to embed the project into the normal business of the parties.

It will ensure that decision-making processes are transparent and equitable and will manage any differences or conflict between the parties.

The Board will be co-chaired by representatives of the parties and comprised of individuals from the parties and others essential to the smooth running of the project. OCCG Voting Membership: Three representatives as nominated by OCCG one of which will be Clinical. OCCG Project Manager will attend the Board in a non-voting capacity, unless deputising for an OCCG voting member. BI Voting Membership: *Medical Affairs, PIO Project Manager and Head of National Policy and Partnerships.* With agreement of voting Board members, additional non-voting members of the Board may be invited to attend Board meetings.

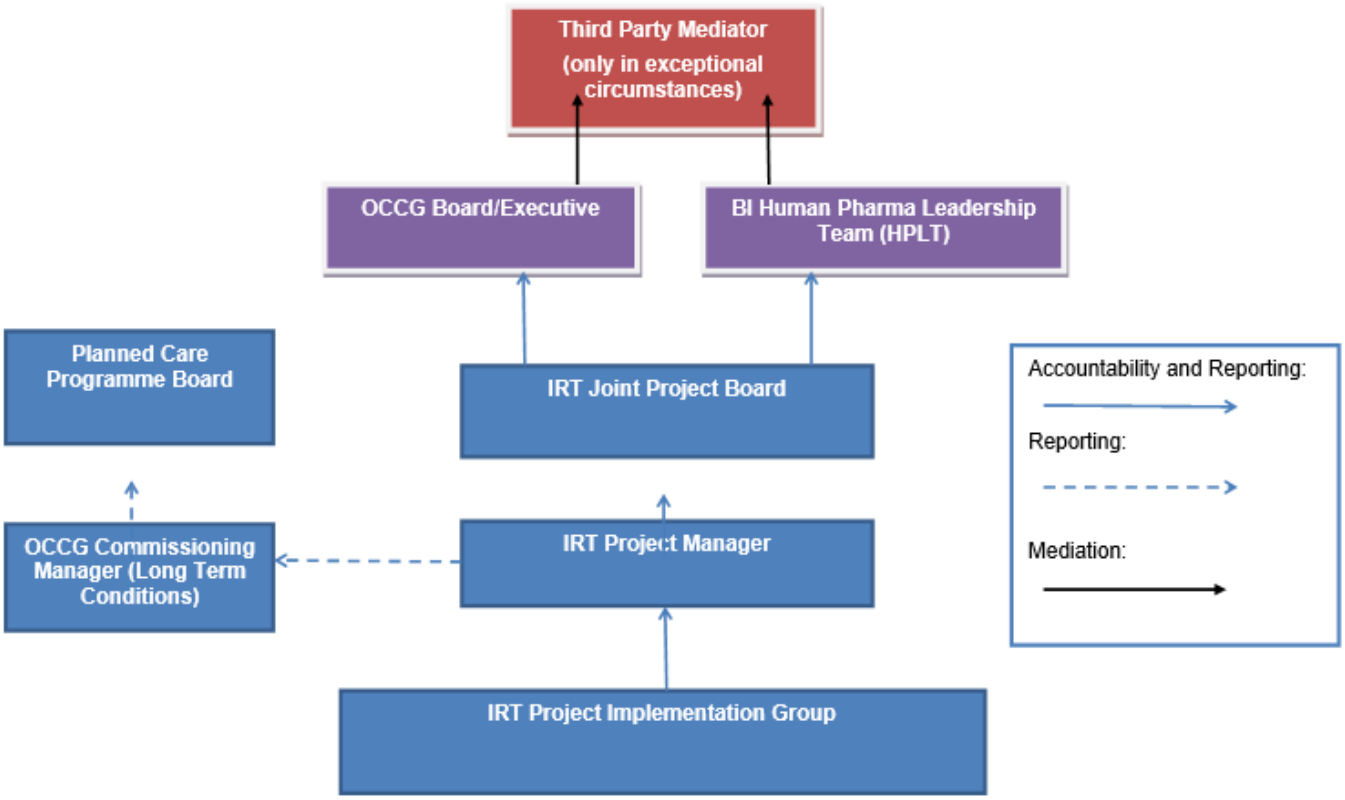
The Board will conduct its business through meetings on a 6-weekly basis, but may meet more frequently as agreed and required. Voting members on the Board will be able to nominate deputies to attend if required due to lack of availability.

In the event of the Board being unable to agree on a decision and where there is a balanced vote, the decision will be escalated for decision and negotiation to the OCCG Board/Executive and the BI HPLT. If the decision remains unresolved after escalation, then a last resort may be the involvement of a third party mediator to help resolve the decision or dispute.

IRT Project Implementation Group

- Membership: Appropriate clinical and managerial representatives from OCCG, BI and the Oxfordshire healthcare providers, including the IRT Project Manager. The IRT Project Implementation Group will include at least one patient who is an expert by experience and establish reliable means to link into relevant patient groups and relevant third sector bodies; the patient representative will be reimbursed for travel costs.
- Purpose: Responsible for the project management and operational delivery of the IRT pilot. This will include delivery of clinical care, as well as management, administration, IT, equipment and facilities to support delivery of the pilot within the agreed project funding. It will also include the collection and analysis of relevant data to inform evaluation of the pilot.
- Accountability: The Project Implementation Group will be accountable to the IRT Joint Project Board.
- Meetings: The Project Implementation Group will meet on a monthly basis, but may meet more frequently as agreed and required.

IRT Governance Framework Model



Appendix C: Project Plan

Phase 0	Sept-Oct 2018	• OCCG Board Approval • BI Approval • Joint Working Agreement (JWA) signed between OCCG and BI • Executive summary for project certified and published on https://www.boehringer-ingelheim.co.uk/
		• Upon signing of the JWA and publication of the executive summary, the following will commence: • Contract variations and Memorandums of Understanding signed between OCCG and health care providers • Primary care record search and template development for use in practices and neighbourhoods • IRT workforce recruitment commences
Phase 1	Nov-Dec 2018	• Start Nov: BI transfers Phase 1 funding contribution to OCCG • Primary care searches are run in some City and North practices in preparation for PRMs • IRT operational premises confirmed and booked • IRT pathways confirmed and communicated to Oxfordshire health system • IRT and Urgent Care/Frailty pathway confirmed. Consistent respiratory admission reporting from hospital trusts to IRT established. • IRT Weekly MDTs commence • IRT workforce recruitment continues • Single point of access/contact for IRT set up • Staff equipment assigned
Phase 2	Jan-April 2019	• Start Jan: BI transfers Phase 2 funding contribution to OCCG • Primary care searches are run in all City and North practices/ neighbourhoods • Primary care PRMs commence • Supported spirometry delivery and training in neighbourhoods commences • Community respiratory outpatients commence • Joint respiratory nurse and practice nurse Asthma/COPD clinics commence • Locality physiotherapy and domiciliary visits for housebound patients • Care and support planning and early EoL identification commences • Education programme planned and booked, with possible commencement
Phase 3	May-Oct 2019	• May: 6 months interim evaluation of pilot • June: BI transfers Phase 3 funding contribution to OCCG • Education programme commences/continues
Phase 4	Nov 2019 – Jan 2020	• Nov: BI transfers Phase 4 funding contribution to OCCG • Nov-Dec: 12 month full evaluation • Jan - Long term funding decision