Meeting of the Joint Committee of Clinical Commissioning Groups (JCCCGs)

Thursday 04 October 2018, 13:00-15:00

South Ribble Borough Council, Civic Centre (Shield Room),

West Paddock, Leyland, Lancashire PR25 1DH

Agenda

Time	Item No	Item	Owner	Action	Format
Standing Items					
13:00	1.	Welcome and Introductions	Chair	Information	Verbal
	2.	Apologies	Chair	Information	Verbal
	3.	Declarations of interests	Chair	Information	Verbal
	4.	a) Minutes public meeting 05 July 2018 b) Minutes public meeting 07 June 2018	Chair	Approval	Attached
	5.	Action Matrix	Chair	Information	Attached
For Discussion/Recommendations					
Improving Population Health					
13:15	6.	Commissioning Policies: a) Policy for the excision of uterus for the management of heavy menstrual bleeding. b) Policy for the management of otitis media with effusion (OME) using grommets c) Policy for commissioning photorefractive surgery for the correction of refractive error d) Policy for Supply and Funding of Insulin Pumps for Patients with Diabetes Mellitus e) Policy for managing back pain- spinal injections and radiofrequency denervation f) Policy for the supply and funding of glucose monitoring devices for patients	E Johnstone	Approval	Attached

		with diabetes mellitus.			
Developing a Joined-up Health and Care System					
14:00	7.	Consultation Framework	G Raphael	Approval	Attached
14:30	8.	Overview: Our Health Our Care (OHOC)	D Gizzi	Information	To follow
14:50	9.	Any other business	Chair	Information	Verbal
Date and time of next meeting: Thursday 01 November 2018, 13:00-15:00, Morecambe Bay CCG, Moor Lane Mills, Lancaster LA1 1QD					

Please send apologies to Gaynor Jones gaynor.jones8@nhs.net

Members of the public are asked to note that the Chair, ICS Chief Officer and Executive Lead for Commissioning will be available for a 30-minute pre-meeting at 12:30 to raise any questions about the agenda for the JCCCGs meeting.

Agenda Item no. 4a

Joint Committee of the Clinical Commissioning Groups (JCCCGs)

Notes of the Joint Committee of the Clinical Commissioning Groups held on Thursday 5th July 13:00 -16:00 at 53 Degrees, University of Central Lancashire, Fylde Road, Preston, PR1 2TQ

Chair	Phil Watson	Independent Chair	JCCCGs	Attended
Voting Members **(One vote per CCG)**	Penny Morris	Chief Clinical Officer	Blackburn with Darwen CCG	Attended
	Roger Parr	Chief Finance Officer	Blackburn with Darwen CCG	Apologies
	Graham Burgess	Chair	Blackburn with Darwen CCG	Attended
	David Bonson	Chief Operating Officer	Blackpool CCG	Apologies
	Roy Fisher	Chair	Blackpool CCG	Attended
	Denis Gizzi	Chief Officer	Chorley South Ribble & Greater Preston CCGs	Apologies
	Matt Gaunt *(Attended on behalf of Denis Gizzi)*	Chief Finance Officer	Chorley South Ribble & Greater Preston CCGs	Attended
	Geoffrey O'Donoghue	Lay Member	Chorley South Ribble CCG	Apologies
	Gora Bangi	Chair	Chorley South Ribble CCG	Apologies
	Phil Huxley	Chair	East Lancashire CCG	Apologies
	Michelle Pilling *(Attended on behalf of Phil Huxley)*	Lay Member Patient & Public Involvement	East Lancashire CCG	Attended
	Mark Youlton	Chief Officer	East Lancashire CCG	Apologies
	Jackie Hanson *(Attended on behalf of Mark Youlton)*	Director of Quality & Performance - Chief Nurse	East Lancashire CCG	Attended
	Tony Naughton	Chief Clinical Officer	Fylde and Wyre CCG	Apologies
	Tom Marland *(Attended on behalf of Tony Naughton)*	GP	Fylde and Wyre CCG	Attended
	Mary Dowling	Chair	Fylde and Wyre CCG	Attended
	Peter Tinson	Chief Operating Officer	Fylde and Wyre CCG	Attended
	Debbie Corcoran	Lay Member for Patient and Public Involvement	Greater Preston CCG	Attended
	Sumantra Mukerji	Chair	Greater Preston CCG	Attended
	Alex Gaw	Clinical Chair	Morecambe Bay CCG	Apologies
	Andrew Bennett	Chief Officer	Morecambe Bay CCG	Attended
	Clive Unitt	Lay Member	Morecambe Bay CCG	Apologies
	Doug Soper	Lay Member	West Lancashire CCG	Apologies
	Mike Maguire *(Attended on behalf of Doug Soper)*	Chief Officer	West Lancashire CCG	Attended
	Paul Kingan	Chief Finance Officer	West Lancashire CCG	Apologies
In Attendance	Dawn Roberts	Representative	Cumbria County Council	Apologies
	Dominic Harrison	Director of Public Health	Blackburn with Darwen Council	Attending
	Harry Catherall	Chief Executive Officer	Blackburn with Darwen Council	Apologies
	Louise Taylor	Director	Lancashire County Council	Apologies
	Neil Jack	Chief Executive	Blackpool Council	Apologies
	Sakthi Karunanithi	Director of Public Health	Lancashire County Council	Attended
	Sayyed Osman	Director of Adult Services	Blackburn with Darwen Council	Attended
	Steve Thompson	Director of Finance	Blackpool Borough Council	Attended
	Allan Oldfield	Chief Executive	Fylde Borough Council	Apologies
	Amanda Doyle	ICS Lead	Healthier Lancashire & South Cumbria	Attended
	Andy Curran	Medical Director	Healthier Lancashire & South Cumbria	Apologies
	Carl Ashworth	Service Director	Healthier Lancashire & South Cumbria	Apologies
	Declan Hadley	Digital Lead	Healthier Lancashire & South Cumbria	Attended
	Gary Raphael	Finance Director	Healthier Lancashire & South Cumbria	Attended
	Gillian Crankshaw	Pathology Collaboration Project Manager	Lancashire & South Cumbria Pathology Partnership	Attended
	Jane Cass	Director of Operations	NHS England	Attended
	Jean Wright	Project Director	Lancashire Teaching Hospitals NHS FT	Attended
	Neil Greaves	Communications & Engagement Manager	Healthier Lancashire & South Cumbria	Attended

	Sir Bill Taylor	Chair	Healthwatch Blackburn with Darwen	Apologies
	Charmaine McElroy	Business Manager to Amanda Doyle	Healthier Lancashire & South Cumbria	Attended
	Sue Hesketh	Office Coordinator	Healthier Lancashire & South Cumbria	Attended
	Talib Yaseen	Executive Director of Transformation	Healthier Lancashire & South Cumbria	Attended

		ACTION
1	**Welcome and Introductions** The Chair welcomed the members of the Committee to the formal meeting and introductions were made. He added that a drop in session for members of the public was held directly before the meeting today, but there would still be an option for the public present to ask questions after the meeting had finished. The Chair took the opportunity to congratulate Blackburn with Darwen Borough Council via Dominic Harrison on being successful in obtaining the Local Government Achievement Award for 2018. The council has been recognised for achievements in community developments. The council has been described as an 'outstanding example of modern local government' which is 'underpinned by strong, consistent and humble leadership and an unwavering mission to put the customer first'.	**Information**
1.1	**Apologies and Quoracy** Apologies were received from members listed above. ***RESOLVED: The Chair noted the apologies and declared the meeting quorate***	**Information**
1.2	**Declarations of Interest** The Chair requested that the members declare any interests relating to items on the agenda. The Chair reminded those present that if, during the course of the discussion, a conflict of interest subsequently became apparent, it should be declared at that point. ***RESOLVED: There were no declarations of interest***	**Information**
2.	**Minutes from previous meetings for ratification** The Chair advised that a comment had been received with regards to the minutes of the last meeting on the 7th June 2018 in terms of them being briefer than in previous months and not necessarily capturing the active engagement of members of the Committee. Specifically with reference to the discussion around Improving Access to Psychological Therapies (IAPT) at the June 2018 meeting, it was discussed that the overarching strategy and outcome measures would be set at an Integrated Care System (ICS) level and contract control and delivery would be at an Integrated Care Partnership (ICP) level. This was stated and agreed, but not recorded so explicitly. Michelle Pilling responded by asking that the IAPT discussion be amended within the minutes to reflect this. . Mary Dowling shared concerns in relation to the briefer minutes but also suggested that if the draft minutes were available in a more timely manner and could be sent out to members of the Committee in advance for comments, then this would reduce discussion time at these meetings and lead to a more accurate record. The Chair asked the Committee if they were content with ratifying the minutes subject to the additional information being added regarding the IAPT discussion. This was agreed. **RESOLVED: The Committee agreed the minutes subject to the amendments regarding the IAPT discussion**	**Agreement**
2.1	**Action Matrix Review** The Chair reviewed the action matrix. All actions were closed	**Information**
3	**Any Other Business Declared:** The Chair asked the members of the Committee if they had any other business they wished to declare for discussion at the end of the meeting. There was no other business declared.	**Information**
4.	**Pathology Update** The Chair invited Jean Wright to deliver this presentation.	**Noting**

	Jean Wright introduced herself to the Committee and advised that the purpose of the presentation today was to apprise the Committee on the progress of the pathology collaboration programme. She explained that the collaboration is made up from a group of provider organisations working together to improve pathology services across Lancashire and South Cumbria. Some of the challenges currently faced by Trusts across the patch in terms of pathology services are in relation to recruitment of specialised staff and affordability of modern technologies and estates. Across most of our Trust sites, estates are in a poor condition and no longer fit for purpose. Jean Wright added that a Strategic Outline Case (SOC) has been produced and the recommendations within the case have been approved by the Trusts as part of the Collaboration Board. The Trusts involved are Blackpool Teaching Hospitals NHS Foundation Trust, Lancashire Teaching Hospitals NHS Foundation Trust and University Hospitals of Morecambe Bay. East Lancashire Hospitals NHS Trust decided to participate in the collaboration after the SOC had been produced and hence their activity was not included in the original document. As part of the approval process NHSI have now asked for this Trust's information to be added. Expected timeline for completion is the end of September 2018. The project team is continuing with the detailed work required to produce an Outline Business Case (OBC) for all four Trusts to deliver a single Pathology Service across Lancashire and South Cumbria. The planned service model would be a pathology hub facility for non-urgent activity delivered outside of core hours. By co-locating services there is an ability to deliver economies of scale and efficiencies. Essential Services Laboratory (ESL), inpatient and emergency work will continue to be delivered on an individual Trust basis, but it is anticipated that the estates will be smaller. Jean Wright explained that as this is largely a non-patient facing service, patients will not see any direct changes in how their care is delivered. She added that Anticoagulant and Phlebotomy services are not included within the remit of the collaboration. Discussions are ongoing as to where the pathology hub will be located. Jean Wright explained that staff engagement has taken place via drop in sessions and written updates via directorates Jean Wright further added that the collaboration will deliver service efficiencies and value for money. She explained that financial models have been developed demonstrating that after payback on capital investment, savings across four Trusts of £11m per annum can be achieved and reinvested in other healthcare services. She added that a capital bid has been awarded to build the hub and develop ESLs and this is expected to be completed within the next three to four years. The Chair thanked Jean Wright for the presentation and asked for any questions. Michelle Pilling asked if there had been any patient involvement with regards to the collaboration. Jean Wright responded by advising that there had been very little patient involvement in the collaboration as these are non-patient facing services and patients will not see any direct changes in their care. Mary Dowling queried who will be commissioning the service and asked the percentage of savings in comparison to the total spend. Mary Dowling also asked for assurances that new innovations not currently included within the collaboration will not be overlooked. Amanda Doyle explained that the collaboration is being commissioned at Lancashire and South Cumbria level.	

	Jean Wright advised that the savings are between 10-15% of the total spend and by doing things differently this will reduce duplication and variation, producing service efficiencies. She added that any new innovations that are not currently in sight will be taken into account as the collaboration develops. Sumantra Mukerji asked with regards to specimen integrity and the plans around transportation of these. He also queried how existing contracts which have a number of years left to run are being handled. Jean Wright responded stating that work is ongoing with transport companies with regards to specimen integrity and with other similar collaboratives to discuss their transport issues and learn from them. She further explained that in respect of existing contracts, this is high on the agenda and discussions are ongoing with current providers. Roy Fisher commented that it would be useful to see the timeline in respect of implementation. .Jean Wright responded by advising that a timeline will be made available for the next pathology update to the Joint Committee of CCGs. Steve Thompson asked regarding the impact this would have on Local Authority Coroners Services. Jean Wright responded to say that mortuary services had not been included within the remit of this process for now and would remain within the Trusts. **RESOLVED: The Committee noted the paper**	
5.	**Preparations for Formal Consultation** The Chair invited Gary Raphael to present this item, Gary Raphael explained that the Lancashire and South Cumbria ICS does not currently have the resources and expertise to be able to design and deliver an effective engagement and consultation programme, sufficient to enable the ICS to conclude formal consultation on service changes in compliance with all regulations, law and best practice. Gary Raphael added that given the urgent need to initiate the necessary work now, it has been decided to buy-in the strategic and operational assistance required, alongside the development of our in-house capabilities. He further explained that it is important to appreciate that the current in-house service has made substantial progress in developing our capabilities. However, moving to formal consultation requires significant resources and expertise which cannot be accommodated within our current staffing resources. Gary Raphael stated that the purpose of the update today is to apprise the Committee of the progress that has been made in securing the necessary expertise and resources needed to undertake formal consultations; He added that the strategic approach will be developed over the next few weeks in between Committee meetings. Mary Dowling expressed that she was happy to support this approach and requested that value for money and best use of resources be referenced in the September update. **RESOLVED: The Committee noted the paper**	**Noting**
6.	**ICS Digital Strategy** The Chair invited Declan Hadley to present this item. Declan Hadley stated that the ICD Digital Strategy was approved on 6th June by the ICS Board. He explained that the content has been developed in partnership with a wide	**Noting**

	stakeholders over several months and that the approach outlined in the strategy focuses on using technology to empower population of Lancashire and South Cumbria in terms of taking an active role in their health, wellbeing and care. Declan Hadley explained that in the future patient data will be used to help prevent, predict and respond to illnesses and conditions. He added that there is a commitment to share information and help patients get the right treatment at the right time, with a strong focus on prevention. Michelle Pilling asked how consent would be obtained from patients with mental health conditions and substance misuse issues. Declan Hadley responded by advising that there are strict new regulations with regards to releasing and sharing data and frontline staff need to start the conversations with all patients to get them engaged in this process. Sumantra Mukerji commented that the more we empower patients the better. He added that there is a lot of variation within general practice in terms of patient empowerment which are opportunities to be maximised. Declan Hadley explained that a tool has been developed called Advice and Guidance which was presented at a recent Care Professionals Board meeting. This tool securely enables GP's and other specialists to connect with other clinicians to determine pathways of care in a digital multi-disciplinary environment. This is automatically updated within the patient Egton Medical Information Systems (EMIS) record. He added that in other areas, this has proven to reduce unnecessary hospital admissions. Declan Hadley explained that we are working with other Exemplar Programmes and GPs are testing various processes and solutions whilst focusing on patient involvement and helping other GP practices come on-line. Mike Maguire commented that the ultimate focus is to keep people healthy and that there are many examples of good practice and resources that we can utilise, such as the Behavioural Insight Team within Public Health. Andrew Bennett queried the level of disruption and change this technology is likely to have within the NHS. Declan Hadley responded by advising that with regards to workforce there are no indications or plans in replacing staff with machines or technology. It is about changing the way we work and empowering patients to take greater control of their care and health and wellbeing, in addition to shaping services in line with the developing technology agenda to enhance care. **RESOLVED: The Committee noted the update**	
7.	**Any Other Business** There was no other business to discuss.	**Information**
8.	**Questions from the Public** **Nick Fogg – 38 Degrees** Q - Nick Fogg felt that the venue was unsuitable for hosting the JCCCGs and commented that this was the second time this venue had been used. Nick Fogg also commented that hard copies of the agenda and papers should be made available for the public at the meeting. A - Phil Watson responded with regards to the venue. He explained that the reason the meeting was held today at this venue, was due to UCLAN hosting an NHS70 celebration to launch the Lancashire and South Cumbria One Health Strategy. He added that Committee members had been invited to the launch of this strategy and so the meeting needed to be within the vicinity. He apologised on the unsuitability of the venue and this will be noted going forward. With regards to hard copies of the agenda and papers for the public, this will be taken into account for future meetings.	**Information**

	Q - Nick Fogg also raised his concern with regards to Fylde Coast Integrated Care Partnership progress and asked whether seminars could be held for the public to fully understand how these partnerships will function. A - Amanda Doyle explained that Integrated Care Partnerships are not new organisations; they are a partnership of existing statutory organisations working more collaboratively together for a defined population (such as the Fylde Coast). She added that the JCCCGs is the formal commissioning function of the Lancashire and South Cumbria ICS. She explained that local engagement events within Integrated Care Partnerships have been held and are planned for the future, which the public are invited and encouraged to attend. She added that if members of the public would like to make any additional suggestions on how they would like to be engaged within their Integrated Care Partnerships or the wider ICS, these would be welcomed. **Hilary Ward – Chorley Campaigner** Q - Hilary Ward asked when the minutes of this meeting would be made available to the public and whether Private Finance Initiatives (PFI) would be used to fund the new builds within the pathology collaboration. A - Gill Crankshaw responded by advising that NHS capital is being used to fund the new builds and PFI will not be used. Phil Watson advised that the minutes of the meeting cannot be approved until ratified at this meeting. He added that the minutes are not always the best way to communicate to the public, as the content can be quite complex and difficult to understand without the wider context. Q - Hilary Ward asked how data sharing will work with private companies. A - Declan Hadley responded that there were strict legislation around data sharing and organisations would not mislead patients by sharing data inappropriately. **Brian Todd** Q - Brian Todd raised his concerns with regards to his understanding that Blackburn with Darwen and East Lancs CCGs were merging. A - Graham Burgess responded to advise that there are no plans to merge the two CCGs. The two CCGs will remain as statutory bodies. There have been discussions however with regards to merging office functions across the CCGs, in order to deliver efficiencies. Q - Brian Todd also raised his concern with regards to the Pennine Healthier Sustainability and Transformation Plan and asked when the public would be consulted on this. A - Graham Burgess responded to advise that numerous meetings have been held with the public to discuss the plan and they will happily forward the feedback from this to Mr Todd. **Graham Burgess agreed to contact Mr Todd with feedback from public engagement events.** **James Clayton – Chorley Campaigner** Q - James Clayton asked whether there should be a public debate with regards to the pathology collaboration. A - Jean Wright responded to say that legal advice had been sought on whether a public consultation is required for the pathology collaboration. It has been advised that as there will be no changes to patient facing services, a public consultation is not required.	

The next JCCCGs Meeting will be held on:
2nd August 2018 (Workshop)
Room 231 Preston Business Centre
13:00 – 15:00

The Chair thanked the Committee members and members of the public for their attendance and closed the meeting

Agenda item no. 4b

Joint Committee of the Clinical Commissioning Groups (JCCCGs)

Notes of the Joint Committee of the Clinical Commissioning Groups
held on Thursday 7th June, 13:00-16:00
at Oswaldtwistle Mills Business Centre, Pickup Street, Oswaldtwistle, Lancashire, BB5 0EY

Chair	Phil Watson	Independent Chair	JCCCGs	Attended
Voting Members **(One vote per CCG)**	Alex Gaw	Chair	Morecambe Bay CCG	Apologies
	Andrew Bennett	Chief Officer	Morecambe Bay CCG	Attended
	David Bonson	Chief Operating Officer	Blackpool CCG	Attended
	Debbie Corcoran	Lay Member for Patient and Public Involvement	Greater Preston CCG	Apologies
	Denis Gizzi	Chief Officer	Chorley South Ribble & Greater Preston CCGs	Attended
	Doug Soper	Lay Member	West Lancashire CCG	Attended
	Geoffrey O'Donoghue	Lay Member	Chorley South Ribble CCG	Apologies
	Gora Bangi	Chair	Chorley South Ribble CCG	Attended
	Graham Burgess	Chair	Blackburn with Darwen CCG	Attended
	Mark Youlton	Chief Officer	East Lancashire CCG	Attended
	Mary Dowling	Chair	Fylde and Wyre CCG	Attended
	Paul Kingan	Chief Finance Officer	West Lancashire CCG	Attended
	Peter Tinson	Chief Operating Officer	Fylde and Wyre CCG	Attended
	Penny Morris	Chief Clinical Officer	Blackburn with Darwen CCG	Attended
	Phil Huxley	Chair	East Lancashire CCG	Attended
	Roy Fisher	Chair	Blackpool CCG	Attended
	Sumantra Mukerji	Chair	Greater Preston CCG	Attended
	Tony Naughton	Chief Clinical Officer	Fylde and Wyre CCG	Apologies
In Attendance	Dawn Roberts	Representative	Cumbria County Council	Attended
	Harry Catherall	Chief Executive Officer	Blackburn with Darwen Council	Apologies
	Louise Taylor	Director	Lancashire County Council	Attended
	Neil Jack	Chief Executive	Blackpool Council	Apologies
	Sakthi Karunanithi	Director of Public Health	Lancashire County Council	Apologies
	Sayyed Osman	Director of Adult Services	Blackburn with Darwen Council	Attended
	Allan Oldfield	Chief Executive	Fylde Borough Council	Apologies
	Dean Langton	Representative	Pendle Borough Council	Apologies
	Gary Hall	Chief Executive Officer	Chorley Council	Apologies
	Kim Webber	Chief Executive Officer	West Lancashire Borough Council	Apologies
	Lawrence Conway	Chief Executive Officer	South Lakeland District Council	Apologies
	Amanda Doyle	ICS Lead	Healthier Lancashire & South Cumbria	Attended
	Andrew Bibby	Director of Specialised Services	NHS England	Attended
	Andy Curran	Medical Director	Healthier Lancashire & South Cumbria	Attended
	Carl Ashworth	Service Director	Healthier Lancashire & South Cumbria	Attended
	Gary Raphael	Finance Director	Healthier Lancashire & South Cumbria	Attended
	Jane Cass	Director of Operations	NHS England	Attended
	Neil Greaves	Communications & Engagement Manager	Healthier Lancashire & South Cumbria	Attended
	Sir Bill Taylor	Chair	Healthwatch Blackburn with Darwen	Apologies
	Charmaine McElroy	Business Manager to Amanda Doyle	Healthier Lancashire & South Cumbria	Attended
	Sue Hesketh	Office Co-Ordinator	Healthier Lancashire & South Cumbria	Attended
	Paul Hopley	Programme Lead for Mental Health	Healthier Lancashire & South Cumbria	Attended

		ACTION
1	**Welcome and Introductions** The Chair welcomed the members of the Committee to the formal meeting. He explained the status of the meeting and that the Committee had invited members of the public to a drop-in session prior to the meeting commencing, in order to give them the opportunity to ask questions in advance and to understand some of the complicated issues to be discussed during this session. He added that there would still be an option to ask questions after the meeting had finished. This meeting had been given extra time as the meeting on 1st March was cancelled as it was not quorate due to the adverse weather conditions experienced on that day. There have been no further meetings of the JCCCGs due to the legal requirements of purdah, associated with Council elections, until today. For the benefit of the public in attendance the Chair explained that this is a meeting of the Joint Committee of CCGs of which there are eight. This Board brings together representatives of all of the eight CCGs.	**Information**
1.1	**Apologies and Quoracy** Apologies were received from members list above. ***RESOLVED: The Chair noted the apologies and declared the meeting quorate***	**Information**
1.2	**Declarations of Interest** The Chair requested that the members declare any interests relating to items on the agenda. The Chair reminded those present that if, during the course of the discussion, a conflict of interest subsequently became apparent, it should be declared at that point. ***RESOLVED: There were no declarations of interest***	**Information**
2.	**Minutes from previous meetings for ratification** There were two comments with regards to amendments to the minutes of the last meeting of the Joint Committee of CCGs held on the 11th January 2018 Page 2 – Declaration of Interest In response to a query as to whether the conflict of interest declared at the January meeting was in line with the recent Conflicts of Interest Guidance, the Chair asked Sumantra Mukerji to explain it again and confirmed that as the conflict did not relate to an item on the agenda for the January meeting, it was appropriate for Dr Mukerji to remain and participate fully in the meeting in January Page 5 (item 4.1) is as follows ***RESOLVED: The Joint Committee agreed to endorse the framework subject to the amendments agreed during the discussion.*** Following these amendments the minutes were ratified by the Board ***RESOLVED: The minutes were ratified.***	**Agreement**
2.1	**Action Matrix Review** The Chair reviewed the action matrix and the following points were discussed: **Mental Health** This is an agenda item at today's meeting and will be presented by Paul Hopley and Andrew Bennett.	**Information**
3	**Any Other Business Declared:** The Chair asked the members of the Committee if they had any other business they wished to declare for discussion at the end of the meeting. Neil Greaves would like to discuss with the Board the plans for the next meeting of the JCCCG in July ***ACTION: This was agreed and to be noted for discussion at the end of the meeting*** The Chair added that there would also be an opportunity for the public to ask questions at the end of the formal meeting.	**Information**

4.	**Outstanding Items from the March 2018 Joint Committee of CCGs** As noted above the meeting on the 1st March was cancelled as it was not quorate due to the adverse weather conditions experienced on that day and there have been no further meetings of the JCCCGs, due to the legal requirements of purdah, until today. Items have been agreed virtually through email by the CCGs due to the inability to bring them together in one room and competing timescales for decisions. The JCCCGs was asked to formally ratify the decisions as outlined on page 3 of the paper. **Resolved: The Board formally ratified the decisions as outlined on page 3 of the paper.** Amanda Doyle announced that the new digital strategy had been launched earlier today at Farrington Lodge. The event had been very well attended with a lot of energy in the room. The strategy looks very good and is a positive step forwards. Amanda Doyle advised that following a competitive selection and interview process that the Executive Directors posts for Lancashire & South Cumbria Integrated Care System had been appointed as follows:- • Gary Raphael Executive Director for Finance and Investment • Andrew Bennett Executive Director of Commissioning • Jackie Hanson Executive Director of Nursing and Care Professionals • Talib Yaseen Executive Director of Transformation Jane Cass has been aligned from NHSE as the Director of Assurance and Delivery and the ICS is currently out to advert for the post of Executive Medical Director.	**For noting**
5.	**Commissioning Development** The Chair invited Andrew Bennett to deliver this item. For the benefit of the public in attendance Andrew Bennett explained that commissioning, in this setting, relates to the planning and buying of services. This forum is not to discuss the provider issues but to agree a commissioning policy. The Commissioning Development Framework is a straight forward place-based model for commissioning. Following a request from the JCCCGs in January 2018, work had been completed on a more detailed and shared understanding of the neighbourhood level of commissioning, based on discussions with representatives from the Fylde Coast, Pennine Lancashire, Central Lancashire, West Lancashire and Morecambe Bay. The paper identified a shared view of the definition of a neighbourhood, the role a neighbourhood will play in a local economy (and in relation to the rest of the system) and some of the benefits a neighbourhood can deliver. A formal implementation plan had been agreed. Staff could be affected therefore there is a need to use a consistent set of principles in order to achieve progress. There is a need to be clear regarding what is being commissioned. The commissioning buying system has been quite fragmented and therefore we need to demonstrate we can work together. It is important that the clinical leads are comfortable that they can deliver on the agenda set out in the paper. Section 5 is the main body of the report which explains the current work undertaken by the various workstreams and specifically how the services will be commissioned. There have been at least 100 people involved in these discussions to date. The paper summarised the detailed work that sits behind all the workstreams. There is a lot of development yet to be done. The final section of the paper covers the governance arrangements and support structures that would allow this to be implemented along with the Clinical Commissioning Board to ensure the 'choreography' is right. The Board welcomed this paper and how this work has engaged our teams; however, it was suggested that this could be more ambitious with regards to the LD and Autism agenda. Healthwatch are carrying out a piece of work around screening and this needs to	**Approval**

	be tied into this piece of work. The Local Authorities expressed their willingness to work with Andrew Bennett on the key joint issues affecting us as a whole system. Andrew Bennett agreed to reference the Local Authorities within the governance section. It was commented that in some workstreams, there appeared to be too many transformation objectives and there was a need for some more local objectives, as there is a tendency for it to look too much like the national strategy. Amanda Doyle responded that there are many national priorities that have to be delivered. For example NHS 111 is a national 'must do' as there is evidence it reduces admissions. NHS 111 must increase the number of clinical responders to help reduce admissions. There are overlaps with Primary Care with regards to the national 'must do's', therefore there is a need to take a pragmatic approach as to how to deal with them. The JCCCGs was asked to approve the following recommendations:- • Note the further development which has taken place on the Commissioning Development Framework and the Mental Health Commissioning Workstream since January 2018 • Note the development work which has taken place across six commissioning workstreams in support of the development of the Lancashire and South Cumbria Integrated Care System and it Integrated Care Partnerships • Approve the proposals for each workstream for the continued implementation of effective commissioning arrangements at the ICS, ICP and neighbourhood levels • Request that the Executive lead for Commissioning for Lancashire and South Cumbria and CCG Accountable Officers continue working together on the implementation of these arrangements, highlighting any risks to the Joint Committee. • Request that the Executive lead for Commissioning identifies the appropriate timescales to request that Governing Bodies receive further recommendations for delegated decision-making into the Joint Committee of CCGs • Receive an update on the implementation process in December 2018 **Resolved: The Board agreed to the recommendations listed above.**	
6.	**Special Educational Needs and Disabilities (SEND) Update** The Chair invited Mark Youlton to introduce this item. Lancashire County Council Children's Services were recently subject to a review of SEND. In response to the review findings during April, Lancashire County Council and its partners submitted a written statement of action to Ofsted and the CQC who jointly evaluated the statement and advised that it was deemed fit for purpose. The statement set out how the local area was going to tackle the significant areas of weakness identified in the report. Twelve priorities were identified within five thematic areas involving all of the appropriate partners, users and carers in the system. At the recent Partnership Board communication was brought up i.e. the use of social media and how this may need to be taken into account in our plans. Mark Youlton will continue to lead on this piece of work with conversations taking place with the County Council and CCGs. There will be various check points across the next few months so we need to ensure the delivery of a consistent approach. Mark explained that the SEND statement of action only related to services delivered by Lancashire County Council. Blackpool and Blackburn with Darwen Councils have, nevertheless, taken the opportunity to consider the issues raised in the Lancashire County Council report and have made improvements to services in the light of the findings. The JCCCGs agreed that this has been a good response to the review of the services. However, a question was asked about how the Joint Committee can be assured that this does not happen again?	**Information**

	Mark Youlton responded to say that regular conversations will be taking place with schools, service users and carers as communication is key. There is a need for the communication to be delivered in the right way to develop trust and as a result of this make this successful. It was suggested that an interim report could be brought to this Board or a peer review in a year's time to provide assurance. **Resolved: The Board acknowledged and agreed this paper.**	
7.	**Mental Health** The Chair invited Paul Hopley and Andrew Bennett to introduce this item. Paul Hopley confirmed that there is still work in progress. Good engagement had taken place with CCGs, Providers, GPs and Local Authorities. Paul was pleased to report that public health colleagues had agreed to undertake a considered health need assessment across the four Local Authorities. Commissioners recognised that current arrangements have been fragmented but are now working together to develop investment plans. Governance structures are also being finalised to support alignment of the workstreams. There was real potential for the agreement of consistent standards and outcomes for mental health care across the ICS in future. Paul also mentioned that the Mental Health Steering Group, Help the Aged and the Digital Lead, Amanda Thornton, had been asked to come together and carry out a gap analysis on a national blue print. He emphasised that Lancashire and South Cumbria has some of the worst social demographics in the country and poorer outcomes are experienced by many of our patients. Demand was increasing and therefore these plans were crucial to our success. There was concern raised with regards to the commissioning workforce due to recent retirements within local teams. This issue will form part of the discussions with the commissioners in future meetings. Andrew Bennett took the opportunity to formally ask Cumbria Partnership Trust to work with Lancashire Care Trust to increase resilience and ensure mental health services are consistent in Cumbria and Lancashire and also help reduce variation across the patch. The Board was asked to endorse the following recommendations: • Note the progress to date as outlined throughout the paper • Approve the final planning geographies as set out in section 2.0 • Approve the proposed governance structure and checkpoints as set out in section 8.0 • Endorse continuation of the Mobilisation Plan **Resolved: The Board endorsed the recommendations**	**For endorsement**
8.	**Any Other Business** Neil Greaves announced that there would be a change to the venue of the next public meeting of the Joint Committee of CCGs in July. The NHS will turn 70 on the 5th July and therefore in order to celebrate this an event is being co organised with the University of Central Lancashire who will host at NHS 70 Tea Party at the University Campus, therefore as the Joint Committee of CCGs is due to take place on the same day the meeting will take place at the venue 53 Degrees. Members of the Joint Committee of CCGs are invited to come along to the celebrations with UCLAN following the meeting at 16:00.	**Information**
The next JCCCG Meeting will be held on: 5th July 2018, 53 Degrees, Fylde Road, Preston, PR1 2TQ		
The Chair thanked the Committee members and members of the public for their attendance and closed the meeting prior to taking questions from members of the public.		

Topics discussed through Public Questions:

NHS 111 Service
The question was raised are there financial penalties that could be implemented if agreed service levels are not met?

There are financial penalties within contracts for providers. The specifications are fairly prescribed. The details of contracts are commercially sensitive and confidential.

Mental Health Mobilisation Plan Progress Report
The question was raised as to how the commissioning process would affect services?

The paper outlines the process for making the commissioning process more efficient and effective. On the 25th June all the commissioners will be brought together to agree a commissioning process by 31st March 2019.

ACTION MATRIX - JCCCGS

Agenda item no. 5

Log No	Meeting Date	Action	Action By	Date By	RAG	Assign to	COMMENTARY
JCCCGs/001	Jun-18	Mental Health Prevention	MH Lead/SK	5.7.18	G		It was agreed that it would be beneficial for the Committee to receive an update on the work around mental health prevention at an appropriate time in the future. **Complete**

KEY:

R	Outstanding
A	Work in progress
G	Complete
	Assigned to XXXX
No	Not due

Agenda Item no. 6

Joint Committee of Clinical Commissioning Groups

Title of Paper	Clinical Commissioning Policy Development: A briefing paper for the Healthier Lancashire and South Cumbria Joint Committee of Clinical Commissioning Groups (JCCCGs)		
Date of Meeting	04.10.2018	Agenda Item	6

Lead Author:	Rebecca Higgs, IFR Policy Development Manager, NHS Midlands and Lancashire CSU	
Purpose of the Report	For Discussion	
	For Information	
	For Approval	X
Executive Summary	The Commissioning Policy Development and Implementation Working Group (CPDIG) has completed a review of a number of intervention specific commissioning policies. Revised and updated policies have been prepared for adoption across Lancashire and South Cumbria. A new policy for the provision of continuous glucose monitoring and flash glucose monitoring devices has also been drafted.	
Recommendations	That the JCCCG ratify Lancashire and South Cumbria policies on the following interventions: - *photorefractive surgery* - *excision of uterus for the treatment of menorrhagia* - *the management of otitis media with effusion (OME) using grommets* - *managing low back pain- spinal injections and radiofrequency denervation* - *provision of insulin pump devices* - *provision of continuous glucose monitoring and flash glucose monitoring devices*	
Equality Impact & Risk Assessment Completed	Yes	
Patient and Public Engagement Completed	Yes	
Financial Implications	Yes	
Risk Identified	No	
If Yes : Risk		
Report Authorised by:	Andrew Bennett	

Midlands and Lancashire
Commissioning Support Unit

Clinical Commissioning Policy Development:

A briefing paper for the Healthier Lancashire and South Cumbria Joint Committee of Clinical Commissioning Groups (JCCCG)

1. Introduction

1.1 The purpose of this paper is to apprise the JCCCG of the work undertaken by the Commissioning Policy Development and Implementation Working Group (CPDIG) to develop commissioning policies on the following interventions:

- *photorefractive surgery*
- *excision of uterus for the treatment of menorrhagia*
- *the management of otitis media with effusion (OME) using grommets*
- *managing low back pain- spinal injections and radiofrequency denervation*
- *the provision of insulin pump devices*
- *continuous glucose monitoring and flash glucose monitoring devices*

2. Development process

2.1 Policy development has been completed in accordance with the process approved by the CPDIG, which has been shared with the JCCCG previously. The development of two of the policies, *the policy for excision of uterus for the treatment of menorrhagia* and *the policy for managing low back pain- spinal injections and radiofrequency denervation,* including the evidence review and criteria setting, commenced under the predecessor Lancashire Commissioning Policies Group (CCG).

2.2 The review process included the following key steps:

- an evidence review by an allocated policy lead;
- clinical stakeholder engagement;
- public and patient engagement;
- notification of local Health, Overview and Scrutiny Committees;
- consideration of any financial implications
- an Equality Impact Risk (EIA) Assessment;
- consultation with Healthier Lancashire and South Cumbria Care Professionals Board (CPB) for clinical assurance purposes.

2.3 Any changes required to the policies in response to feedback received throughout the consultative process were made at the relevant development stage.

2.4 The final policies are available to view via the following links:

Policy for Commissioning Photorefractive Surgery for the Correction of Refractive Error

https://csucloudservices.sharepoint.com/:b:/s/CSU/IFR/EcWejAQzWxFBgSJOCKadmjYBdNl0cCG6_vBXgutEAJKRqQ?e=s80j2F

Policy for Excision of Uterus for the Treatment of Menorrhagia

https://csucloudservices.sharepoint.com/:b:/s/CSU/IFR/Ea477U82A_dPjM5czAYobj0Bo8SSxLaZWS8BlnlqsLORuQ?e=UtJ5Nm

Policy for the Management of Otitis Media with Effusion (OME) using Grommets

https://csucloudservices.sharepoint.com/:b:/s/CSU/IFR/EZQVDbqf8vhLkxmiMTPKTZQBBaJadeq3R2iGSzWbPEk2sg?e=FVDccL

Policy for Managing Low Back Pain- Spinal Injections and Radiofrequency Denervation

https://csucloudservices.sharepoint.com/:b:/s/CSU/IFR/EW_ii-cUs6JGr5i6HTBc8FsBZ7zKfW5Fucmb5ANo2GYvAw?e=UVIuQI

Policy for the Provision of Insulin Pump Devices
https://csucloudservices.sharepoint.com/:b:/s/CSU/IFR/EReIqkL0y3FLkcUnZ1kZVcwBSrpfB83TUXiG1RY4AM5CyA?e=g0VvgN

Policy for the Provision of Continuous Glucose Monitoring and Flash Glucose Monitoring Devices

https://csucloudservices.sharepoint.com/:b:/s/CSU/IFR/EeTcsxub5xNIqHOCpnLy35gBDQbkowfh2NvZjGQM5T0enA?e=Ms9da0

3. Policy for Commissioning Photorefractive Surgery for the Correction of Refractive Error

3.1 This policy has been developed as the existing CCG policies for this intervention have reached their review dates. The review intended to ensure the policy continued to reflect the existing evidence base and CCG commissioning intentions.

3.2 No changes were made to the policy criteria as a result of either the evidence review or clinical engagement and clinicians were supportive of the policy. The CPB supported the development of the policy, pending the outcome of public engagement.

3.3 Neither the public engagement, nor the final stage one EIA[1] identified any changes required to the policy when they were presented to the CPDIG on 16.08.2018. As a result, the policy criteria remain unchanged and the group agreed the policy should proceed to ratification.

3.4 As no changes have been made to the policy, the CPDIG anticipate existing activity and expenditure levels will be unaffected by this policy.

4. Policy for the Excision of Uterus for the Treatment of Menorrhagia

4.1 This policy has been developed as the existing CCG policies for this intervention have reached their review dates. The review intended to ensure the policy continued to reflect the existing evidence base and CCG commissioning intentions.

4.2 No changes were made to the policy criteria as a result of either the evidence review or clinical engagement and clinicians were supportive of the policy. The CPB supported the development of the policy, pending the outcome of public engagement.

4.3 Neither the public engagement, nor the final stage two EIA[2] identified any changes required to the policy when they were presented to the CPDIG on 16.08.2018. As a result, the policy criteria remain unchanged and the group agreed the policy should proceed to ratification.

4.4 As no changes have been made to the policy, the CPDIG anticipate existing activity and expenditure levels will be unaffected by this policy.

5. Policy for the Management of OME using Grommets

5.1 This policy has been developed as the existing CCG policies for this intervention have reached their review dates. The review intended to ensure the policy continued to reflect the existing evidence base and CCG commissioning intentions.

5.2 No material changes were made to the policy criteria as a result of either the evidence review or clinical engagement. The CPB supported the development of the policy, pending the outcome of public engagement, subject to the removal of wording assigning responsibility for observation of hearing loss to the primary care sector.

5.3 Neither the public engagement, nor the final stage two EIA[3] identified any changes required to the policy when they were presented to the CPDIG on 16.08.2018. As a result, the policy criteria remain unchanged and the group agreed the policy should proceed to ratification.

5.4 As no changes have been made to the policy, the CPDIG anticipate existing activity and expenditure levels will be unaffected by this policy.

6. Policy for Managing Low Back Pain- Spinal Injections and Radiofrequency Denervation

6.1 This policy was originally developed by the Pennine Lancashire CCGs as they recognised back pain injections were an area of high activity and expenditure for them. It was subsequently identified that this position was common across the whole of Lancashire and South Cumbria and that there was variation in existing policies. The predecessor group, the CPG, therefore agreed that consideration should be given to collaborative implementation of this policy.

6.2 The policy is expected to ensure clinical practice is aligned with the prevailing national guidance on the management of low back pain. This will include criteria which will aid the identification of patients who will benefit from radiofrequency denervation, which offers the potential for prolonged benefit.

6.3 The policy underwent extensive clinical engagement, including a review by the North West Coast Strategic Clinical Network. A number of changes were made to the policy to aid understanding and clarify the scope; however, the core eligibility criteria remain unchanged from those in the existing Pennine Lancashire policy.

6.4 The CPB supported the development of the policy, pending the outcome of public engagement.

6.5 The introduction of a consistent policy is expected to have a positive impact on expenditure and reduce overall spending on back pain injections across the sub-region. A financial impact analysis was therefore undertaken, which demonstrated that a minimum cost reduction of £315,000 could be expected across Lancashire and South Cumbria. The analysis was presented to Healthier Lancashire and South Cumbria's Finance Investment Group (FIG) on 13.07.2018 when the group supported the ongoing development of the policy and acknowledged the anticipated cost reduction.

6.6 Neither the public engagement, nor the final stage two EIA[4] identified any changes required to the policy when they were presented to the CPDIG on 16.08.2018. As a result, the policy criteria remain unchanged and the group agreed the policy should proceed to ratification.

7. Policy for the Provision of Insulin Pump Devices

7.1 This policy has been developed as it was identified that the existing provision of insulin pump devices in Lancashire and South Cumbria may be marginally lower than that estimated by the National Institute for Health and Care Excellence (NICE) in their technology appraisal guidance costing template. It was recognised that previously there was variation in provision between paediatric and adult patients, with a general trend for under-provision of insulin pumps to adults and over-provision of insulin pumps for children.

7.2 It is recognised that the insulin pump guidance relating to children and young people in the existing, mandatory NICE Technology Appraisal Guidance, TAG151, is unclear. Therefore, the provision of a policy will address the existing variation outlined above, by offering clinicians clear guidance to aid the identification of suitable paediatric patient cohorts who will achieve the greatest clinical benefit from treatment. Only NHS Blackpool CCG has an existing policy in place.

7.3 The policy underwent extensive clinical engagement across stakeholder organisations, including primary and secondary care and the Lancashire Medicines Management Group (LMMG). The CPB supported the development of the policy, pending the outcome of public engagement.

7.4 The CPDIG were presented with the outcome of the 6 week public engagement period on 19.07.2018. Several changes were made to the policy in response to feedback received; the overall effect of these changes was to make the devices available to more patients than was originally proposed.

7.5 A stage two EIA[5] has been undertaken and no concerns were identified.

7.6 A review of the anticipated financial impact of the policy demonstrated that overall expenditure is expected to remain static, but the cost distribution between patient groups will change to reflect more appropriate division of provision between suitable patient cohorts.

8. Policy for the Provision of Continuous Glucose Monitoring (CGM) and Flash Glucose Monitoring (FSM) Devices

8.1 The CPDIG agreed that a collaborative policy on the provision of CGM devices was required to address existing variation in access criteria for the devices across the sub-region.

8.2 The CPDIG approved the inclusion of FSM devices in the scope of the policy in December 2017, at the request of the LMMG. Following consultation, the LMMG had agreed in December 2017 that the recommendations in the non-mandatory national guidance produced by the Regional Medicines Optimisation Committee (RMOC) on the provision of FSM devices should not be followed. It was therefore agreed that due to the similarities between FSM and CGM devices a unified policy covering both interventions was necessary to:

- Ensure clinicians have a single piece of clear guidance regarding the provision of both types of glucose monitoring devices.

- Enable the provision of access to new technology, FSM, to the patient cohorts who will achieve the greatest clinical benefit from treatment, in line with the emerging evidence base.

8.3 The policy underwent extensive clinical engagement across stakeholder organisations, including primary and secondary care and the LMMG. The CPB supported the development of the policy, pending the outcome of public engagement.

8.4 As it is anticipated there will be a cost implication to CCGs associated with the introduction of this policy, a financial impact analysis was undertaken. Following discussions at the CPDIG, a paper on the potential financial impact was presented to FIG in April 2018. This advised that, if the existing level of CGM provision is more closely aligned to patient eligibility defined in the proposed CGM policy, this will introduce a cost pressure of between £238,500 and £278,500 per annum across the sub-region.

8.5 FIG was advised that, although neither the gross annual cost of FSM, or the associated savings that may be generated through FSM, can be accurately estimated in advance of policy implementation due to the paucity of the available data, the approximate gross annual cost to the local health economy of the provision of FSM in line with the draft policy is expected to be £472,750. This cost is expected to be offset by savings made by reducing the requirement for blood glucose monitoring by traditional means and a reduction in short-term diabetic complications. However, it was noted that an analysis of the net cost to the local health economy if the technology is introduced without policy controls estimated the net cost to Lancashire and South Cumbria would be approximately £1,627,000.

8.6 The maximum estimated cost pressure associated with the introduction of this policy is therefore £751,250. FIG supported the ongoing development of the policy and acknowledged the anticipated increase in costs.

8.7 The CPDIG were presented with the outcome of the 6-week public engagement period on 19.07.2018. Several changes were made to the policy in response to feedback received; the overall effect of these changes was to make the devices available to more patients than was originally proposed.

8.8 A stage two EIA[6] has been undertaken and no concerns were identified.

9. Conclusion

9.1 The JC CCG is asked to ratify the following collaborative commissioning policies, which will replace any existing CCG policies:

- *Policy for Commissioning Photorefractive Surgery for the Correction of Refractive Error*
- *Policy for Excision of Uterus for the Treatment of Menorrhagia*
- *Policy for the Management of Otitis Media with Effusion (OME) using Grommets*
- *Policy for Managing Low Back Pain- Spinal Injections and Radiofrequency Denervation*
- *Policy for the Provision of Insulin Pump Devices*
- *Policy for the Provision of Continuous Glucose Monitoring and Flash Glucose Monitoring Devices*

Elaine Johnstone, Chair of the CPDIG

25.09.2018

References

1. Equality Impact and Risk Assessments, Pan Lancashire Policy Review for Commissioning Photorefractive Surgery for the Correction of Refractive Error, 10.08.2018 *https://csucloudservices.sharepoint.com/:b:/s/CSU/IFR/EYwLEZjhB6FKratJbUb8nBoBNLyPln_1pC5kd4NzY30b4g?e=3fp3j0*
2. Equality Impact and Risk Assessment Stage 2 for Policies, Pan Lancashire Policy Review, Policy for the Excision of the Uterus, 07.08.2018 *https://csucloudservices.sharepoint.com/:b:/s/CSU/IFR/ER8zbN3ZQbBBn8PBKPEQYKoB3_tYrpaIvKW2FfJKjdgkqw?e=5KSAqf*
3. Equality Impact and Risk Assessments, Pan Lancashire and South Cumbria Review, Policy for the Management of Otitis Media with Effusion using Grommets, 10.08.2018 https://csucloudservices.sharepoint.com/:b:/s/CSU/IFR/EZLH_W6v6D9Duvzd_K3ZZJQB-gkcpHMp-tTu6e07cCDhwQ?e=5kibau
4. Equality Impact and Risk Assessment Stage 2 for Policies, Policy for Managing Back Pain-Spinal Injections and Radiofrequency Denervation, 07.08.2018 https://csucloudservices.sharepoint.com/:b:/s/CSU/IFR/EWrg_s3zP0FCsLINprAtu7gB-3kZRUenzw89opb5DI3A1A?e=qneLnN
5. Equality Impact and Risk Assessment Stage 2 for Policies, Policy for the Supply and Funding for Insulin Pumps for Patients with Diabetes Mellitus, 07.08.2018 https://csucloudservices.sharepoint.com/:b:/s/CSU/IFR/ESwjjUntoAhPr6LvUaEszMABb9-D9zLLkINo_kPQIhn6Jw?e=0kNUFq
6. Equality Impact and Risk Assessment Stage 2 for Policies, Policy for the Provision of Continuous Glucose Monitoring and Flash Glucose Monitoring Devices for Patients with Diabetes Mellitus, 07.08.2018 https://csucloudservices.sharepoint.com/:b:/s/CSU/IFR/Eb7c6Qfpti1KrqhlctrVoVMBgfk_hkAFDCKCtLP_tddFaA?e=JAHdd3

Policy for the commissioning of Excision of the Uterus for the treatment of menorrhagia (heavy menstrual bleeding)		
	Version No.	**Changes Made**
Version of: August 2018	V0.5	OPCS/ICS codes added
Version of July 2018	V0.4	References updated to reflect current NICE guidance following further review.
Version of: January 18	V0.3	Policy criteria moved to beginning of policy – in line with feedback from JCCCG
Version of: September 17	V0.2	Wording at section 8.2 changed to provide clarity that all criteria must be fulfilled.
Original draft: 24.07.2017	V0.1	Based on existing pan-Lancashire policy

Lancashire and South Cumbria Clinical Commissioning Groups (CCGs)

Policies for the Commissioning of Healthcare

Policy for the commissioning of Excision of the Uterus for the treatment of menorrhagia (heavy menstrual bleeding)

	This document is part of a suite of policies that the CCG uses to drive its commissioning of healthcare. Each policy in that suite is a separate public document in its own right, but will be applied with reference to other policies in that suite.
1	**Policy Criteria**
1.1	The CCG will commission hysterectomy for patients with suspected malignancy without a need for prior approval for funding.
1.2	The CCG will commission excision of the uterus when ALL of the following criteria are satisfied:
1.2.1	• The woman presents with HMB (defined by the woman's subjective assessment of excessive menstrual blood loss, which interferes with the woman's physical, emotional, social and material quality of life) and a full history is available to exclude co-morbidities and other underlying causes.
	AND
1.2.2	• Other treatment options for HMB, dysmenorrhoea and/or symptomatic large or multiple fibroids (i.e. levonorgestrel intrauterine system; tranexamic acid; other hormonal methods injected progesterone's, combined oral contraceptives, GnRH analogue etc) have failed, are contraindicated or have been declined by the woman after all information and side effects of the possible treatments have been explained to her.
	AND
1.2.3	• There is a wish for amenorrhoea (absence of menstruation)
	AND
1.2.4	• The woman (who has been fully informed) requests hysterectomy
	AND
1.2.5	• The woman no longer wishes to retain her uterus and fertility
2	**Scope and definitions**
2.1	This policy is based on the CCGs Statement of Principles for Commissioning of Healthcare (version in force on the date on which this policy is adopted).
2.2	Excision of the uterus (hysterectomy) is an intervention for people who are severely affected with menorrhagia (heavy menstrual bleeding [HMB]).
2.3	The scope of this policy includes requests for excision of the uterus (hysterectomy) for the treatment of HMB.
2.4	The scope of this policy does not include requests for excision of the uterus

	for the treatment of conditions other than HMB.
2.5	The CCG recognises that a patient may have certain features, such as • having HMB; • wishing to have a service provided for HMB, • being advised that they are clinically suitable for excision of the uterus, and • being distressed by their HMB, and by the fact that that they may not meet the criteria specified in this commissioning policy. Such features place the patient within the group to whom this policy applies and do not make them exceptions to it.
2.6	For the purpose of this policy the CCG defines HMB according to NICE's Clinical Guideline (CG) 44 as "excessive menstrual blood loss which interferes with the woman's physical, emotional, social and material quality of life, and which can occur alone or in combination with other symptoms. Excision of the uterus refers to the surgical removal (abdominal or vaginal) of the uterus"[1].
2.7	The criteria outlined in this policy are based on NICE's guideline CG44 "Heavy menstrual bleeding: assessment and management"[1]
3	**Appropriate Healthcare**
3.1	The purpose of excision of the uterus is normally to resolve HMB by removing the uterus, which causes amenorrhea (absent periods).
3.2	The CCG regards the achievement of this purpose as according with the Principle of Appropriateness. Therefore, this policy does not rely on the principle of appropriateness. Nevertheless if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider the principle of appropriateness in the particular circumstances of the patient in question before confirming a decision to provide funding.
4	**Effective Healthcare**
4.1	The effectiveness of Hysterectomy for people who are severely affected by HMB is well documented and defined within National Institute for Health and Clinical Excellence (NICE) Guidance's CG44[1].
4.2	For people who are not severely affected by HMB, any benefit from hysterectomy is outweighed by the morbidity associated with surgery
5	**Cost Effectiveness**
5.1	The CCG does not call into question the cost-effectiveness of excision of the uterus and therefore this policy does not rely on the Principle of Cost-

	Effectiveness. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the treatment is likely to be Cost Effective in this patient before confirming a decision to provide funding.
6	**Ethics**
6.1	The CCG does not call into question the ethics of excision of the uterus and therefore this policy does not rely on the Principle of Ethics. Nevertheless if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the treatment is likely to raise ethical concerns in this patient before confirming a decision to provide funding.
7	**Affordability**
7.1	The CCG does not call into question the affordability of excision of the uterus and therefore this policy does not rely on the Principle of Affordability. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the treatment is likely to be affordable in this patient before confirming a decision to provide funding.
8	**Exceptions**
8.1	The CCG will consider exceptions to this policy in accordance with the Policy for Considering Applications for Exceptionality to Commissioning Policies.
9	**Force**
9.1	This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance relating to this intervention, or to alternative treatments for the same condition.
9.2	In the event of NICE guidance referenced in this policy being superseded by new NICE guidance, then: • If the new NICE guidance has mandatory status, then that NICE guidance will supersede this policy with effect from the date on which it becomes mandatory. • If the new NICE guidance does not have mandatory status, then the CCG will aspire to review and update this policy accordingly. However, until the CCG adopts a revised policy, this policy will remain in force and any references in it to NICE guidance will remain valid as far as the decisions of this CCG are concerned.
10	**References**
	1. NICE guideline: Heavy menstrual bleeding: assessment and management. Published: 14 March 2018 www.nice.org.uk/guidance/ng88

Appendix 1: Associated OPCS/ICD codes

The codes applicable to this policy are:

OPCS codes	ICD codes
Q072, Q074, Q075, Q076, Q078, Q079	N924, N920, N921, N922

Date of adoption
Date for review

Policy for the management of otitis media with effusion (OME) using grommets		
	Version Number:	**Changes Made:**
September 2018	V0.6	- Final draft, relevant OPCS code added.
29.06.2018	V0.5	- Wording at criterion a) further amended to remove reference to documented period of active observation in primary care following June CPDIG to reflect feedback that key issue is persistence of hearing loss. - Wording at bullet point 1 of section 4.1 amended to provide clarity.
14.06.2018	V0.4	- Wording at criterion a amended to remove reference to OME and to change point of diagnosis to point of presentation following CPB feedback.
14.05.2018	V0.3	- Policy criteria moved to section 1 in line with revised format. - Removal of reference to items that aren't directly commissioned by CCGs in line with previous directive of working group.
30.11.2017	V0.2	"AND EITHER" added between criteria C and D for clarity.
Original Draft: 15.11.2017	V0.1	Initial draft prepared following evidence review

Lancashire and South Cumbria Clinical Commissioning Groups (CCGs)

Policies for the Commissioning of Healthcare

Policy for the management of otitis media with effusion (OME) using grommets

	Introduction
	This document is part of a suite of policies that the CCG uses to drive its commissioning of healthcare. Each policy in that suite is a separate public document in its own right but will be applied with reference to other policies in that suite.
1	**Policy**
1.1	The CCG will commission the surgical management of OME using grommets when the following criteria are satisfied: a) The patient is under 12 years of age.
	AND
	b) Hearing loss has persisted over a period of at least three months.
	AND EITHER
	c) The patient has a hearing level in the better ear of 25-30dBHL or worse averaged at 0.5,1,2 and 4kHz
	OR
	d) Exceptionally, where there is well documented evidence that a hearing loss of less than 25-30 dBHL is having a significant impact on the child's developmental, social or educational status.
1.2	OME in children with Down's syndrome or a cleft palate is unlikely to improve without further management and hearing loss may exacerbate existing communication problems. Patients with Down's syndrome or cleft palate who are suspected of having OME should be referred for specialist assessment immediately by an MDT with expertise in assessing and treating these children[1,2,3]. Following referral, the management of OME in children with Down's syndrome or cleft palate should be carried out in line with the specific guidance in NICE CG60[1].
1.3	The CCG will not routinely commission adjuvant adenoidectomy in the absence of persistent and/or frequent upper respiratory tract symptoms.
2	**Scope and definitions**
2.1	This policy is based on the CCGs Statement of Principles for Commissioning of Healthcare (version in force on the date on which this policy is adopted).
2.2	The insertion of grommets is a surgical procedure where a small tube (a tympanostomy tube, also known as a grommet or myringotomy tube) is

	inserted into the eardrum in order to keep the middle ear aerated for a prolonged period of time, and to prevent the accumulation of fluid in the middle ear.
2.3	The scope of this policy includes requests for the management of OME using grommets.
2.4	The CCG recognises that a patient may have certain features, such as • having OME • wishing to have a service provided for their OME, • being advised that they are clinically suitable for the insertion of grommets, and • be distressed by their OME and by the fact that that they may not meet the criteria specified in this commissioning policy. Such features place the patient within the group to whom this policy applies and do not make them exceptions to it. The CCG note that the evidence demonstrates that if grommets are not inserted within 12-18 months of presentation there is no difference in hearing between treated and untreated patients.
2.5	For the purpose of this policy the CCG defines OME as the accumulation of fluid within the middle ear space resulting in hearing impairment.
2.6	National Institute for Health and Care Excellence (NICE) guidance on the management of OME in children under twelve exists.[1]
3	**Appropriate Healthcare**
3.1	The purpose of grommet insertion is normally to allow air to pass into the middle ear, preventing the accumulation of fluid and allowing hearing to return to normal.
3.2	The CCG regards the achievement of this purpose as according with the Principle of Appropriateness. Therefore this policy does not rely on the principle of appropriateness. Nevertheless if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider the principle of appropriateness in the particular circumstances of the patient in question before confirming a decision to provide funding.
4	**Effective Healthcare**
4.1	The following policy criteria rely on the principle of appropriateness: • The criterion relating to children and adults over 12 as the CCG considers the evidence of the greatest benefit is in those under the age of 12 years. • The criterion relating to the requirement for persistent hearing loss as the CCG considers that for patients who are not severely affected by OME any potential benefit from the intervention is outweighed by the morbidity associated with surgery.

5	**Cost Effectiveness**
5.1	The CCG does not call into question the cost-effectiveness of the surgical management of OME and therefore this policy does not rely on the Principle of Cost-Effectiveness. Nevertheless if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the treatment is likely to be Cost Effective in this patient before confirming a decision to provide funding.
6	**Ethics**
6.1	The CCG does not call into question the ethics of the surgical management of OME and therefore this policy does not rely on the Principle of Ethics. Nevertheless if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the treatment is likely to raise ethical concerns in this patient before confirming a decision to provide funding.
7	**Affordability**
7.1	The CCG does not call into question the affordability of the surgical management of OME and therefore this policy does not rely on the Principle of Affordability. Nevertheless if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the treatment is likely to be affordable in this patient before confirming a decision to provide funding.
8	**Exceptions**
8.1	The CCG will consider exceptions to this policy in accordance with the Policy for Considering Applications for Exceptionality to Commissioning Policies.
8.2	In the event of inconsistency, this policy will take precedence over any non-mandatory NICE guidance in driving decisions of this CCG. A circumstance in which a patient satisfies NICE guidance but does not satisfy the criteria in this policy does not amount to exceptionality.
9	**Force**
9.1	This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance relating to this intervention, or to alternative treatments for the same condition.
9.2	In the event of NICE guidance referenced in this policy being superseded by new NICE guidance, then: • If the new NICE guidance has mandatory status, then that NICE guidance will supersede this policy with effect from the date on which it becomes mandatory. • If the new NICE guidance does not have mandatory status, then the CCG will aspire to review and update this policy accordingly. However, until

	the CCG adopts a revised policy, this policy will remain in force and any references in it to NICE guidance will remain valid as far as the decisions of this CCG are concerned.
10	**References**
	1. NICE Clinical Guidance (CG) 60, Otitis media with effusion in under 12s: surgery https://www.nice.org.uk/guidance/cg60 2. NICE Clinical Knowledge Summaries (CKS) Otitis media with effusion Scenario: Management https://cks.nice.org.uk/otitis-media-with-effusion#!scenario 3. NHS Choices, Glue Ear https://www.nhs.uk/conditions/glue-ear/treatment/

Appendix 1: Associated OPCS codes

The codes applicable to this policy are:

OPCS codes
D151

Date of adoption
Date for review

Policy for commissioning photorefractive surgery for the correction of refractive error		
	Version Number:	**Changes Made:**
Version of August 2018	V0.8	Policy realigned to CPDIG template following patient engagement for consistency. OPCS/ICD codes added.
Version of 15.06.18	V0.7	Amends after review at Working Group
Version of 17.05.2018	V0.6	Amends after review at Working Group
Version of: 14.05.2018	V0.5	Amends after review of consultation responses
Version of: 26.01.2018	V0.4	Policy criteria moved to beginning of policy following feedback from JCCG
Version of: 12.01.2018	V 0.3	Correction of numbering and grammatical errors.
Version of: 30.11.2017	V 0.2	Removal of the word “laser” and reference to treatment of other conditions such as diabetic retinopathy in line with November CPDIG directive
Original Draft: 15.11.2017	V 0.1	Initial draft prepared following evidence review

Lancashire and South Cumbria Clinical Commissioning Groups (CCGS)

Policies for the Commissioning of Healthcare

Policy for commissioning photorefractive surgery for the correction of refractive error

	This document is part of a suite of policies that the CCG uses to drive its commissioning of healthcare. Each policy in that suite is a separate public document in its own right but will be applied with reference to other policies in that suite.
1	**Policy Criteria**
1.1	The CCG considers that surgery for the correction of refractive error does not accord with the Principle of Appropriateness, therefore the CCG will not routinely commission this intervention.
2	**Scope and definitions**
2.1	This policy is based on the CCG's Statement of Principles for Commissioning of Healthcare (version in force on the date on which this policy is adopted).
2.2	Photorefractive surgery is a procedure to correct visual refractive error.
2.3	The scope of this policy includes but is not limited to requests for surgery to correct myopia, hyperopia, astigmatism and presbyopia including: • Photorefractive keratectomy (PRK) • Laser in-situ keratomileusis (LASIK) • Laser assisted subepithelial keratomileusis (LASEK) • Laser assisted subepithelial keratomileusis with corneal collagen cross linking (LASEK-CXL) • Small incision lenticule extraction (SMILE)
2.4	The CCG recognises that a patient may have certain features, such as; • having a refractive error due to myopia, hyperopia, astigmatism or presbyopia; • wishing to have a service provided for their refractive error • being advised that they are clinically suitable photorefractive surgery and • be distressed by their refractive error and by the fact that that they may not meet the criteria specified in this commissioning policy. Such features place the patient within the group to whom this policy applies and do not make them exceptions to it.

3	**Appropriate Healthcare**
3.1	The purpose of photorefractive surgery is normally to correct a patient's refractive error, removing or reducing the requirement for glasses or contact lenses. However corrective surgery is considered a cosmetic treatment and compared to the use of spectacles or contact lenses, not an efficient use of NHS resources.
3.2	This policy relies on the criterion of appropriateness in that the CCG considers that other services competing for the same CCG resource more clearly have a purpose of preserving life or of preventing grave health consequences.
4	**Effective Healthcare**
4.1	The CCG does not call into question the effectiveness of photorefractive surgery and therefore this policy does not rely on the Principle of Effectiveness. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the purpose of the treatment is likely to be achieved in this patient without undue adverse effects before confirming a decision to provide funding.
5	**Cost Effectiveness**
5.1	The CCG does not call into question the cost-effectiveness of photorefractive surgery and therefore this policy does not rely on the Principle of Cost-Effectiveness. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the treatment is likely to be Cost Effective in this patient before confirming a decision to provide funding.
6	**Ethics**
6.1	The CCG does not call into question the ethics of photorefractive surgery and therefore this policy does not rely on the Principle of Ethics. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the treatment is likely to raise ethical concerns in this patient before confirming a decision to provide funding.
7	**Affordability**
7.1	The CCG does not call into question the affordability of photorefractive surgery and therefore this policy does not rely on the Principle of Affordability. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the treatment is likely to be affordable in this patient before confirming a decision to provide funding.
8	**Exceptions**
8.1	The CCG will consider exceptions to this policy in accordance with the Policy for Considering Applications for Exceptionality to Commissioning Policies.

8.2	In the event of inconsistency, this policy will take precedence over any non-mandatory NICE guidance in driving decisions of this CCG. A circumstance in which a patient satisfies NICE guidance but does not satisfy the criteria in this policy does not amount to exceptionality.
9	**Force**
9.1	This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance relating to this intervention, or to alternative treatments for the same condition.
9.2	In the event of NICE guidance referenced in this policy being superseded by new NICE guidance, then: • If the new NICE guidance has mandatory status, then that NICE guidance will supersede this policy with effect from the date on which it becomes mandatory. • If the new NICE guidance does not have mandatory status, then the CCG will aspire to review and update this policy accordingly. However, until the CCG adopts a revised policy, this policy will remain in force and any references in it to NICE guidance will remain valid as far as the decisions of this CCG are concerned.

Appendix 1: Associated OPCS/ICD codes

The codes applicable to this policy are:

OPCS codes	ICD codes
C442, C444, C445	H442, H521, H522, H524

Date of adoption
Date for review

Policy for Supply and Funding of Insulin Pumps for Patients with Diabetes Mellitus		
	Version No.	**Changes Made**
Version of July 2018	V0.5	Changes made to the policy following patient engagement including: - the inclusion of treatment for patients with non-type 2 diabetes caused by the absence of insulin production; - clear eligibility criteria for patients who initiated treatment privately - change to the threshold related to carbohydrate counting.
Version of May 2018	V0.4	Criteria moved to the beginning of the policy in line with other policies.
Version of: 01.03.2018	V 0.3	Clarity provided to section 2 following CPB surrounding the types of clinicians who can initiate/supply pump therapy
Version of: 16.02.2018	V 0.2	Amendments made to the policy in line with discussions at the CPDIG following the stage 3 review
Version of: December 2017	V 0.1	Policy drafted.

Lancashire and South Cumbria Clinical Commissioning Groups (CCGs)

Policies for the Commissioning of Healthcare

Policy for the Supply and Funding of Insulin Pumps for Patients with Diabetes Mellitus

	This document is part of a suite of policies that the CCG uses to drive its commissioning of healthcare. Each policy in that suite is a separate public document in its own right, but will be applied with reference to other policies in that suite.
1	**Policy Criteria**
1.1	Insulin pump therapy must be must be initiated and continually supplied / prescribed by specialist clinicians (Diabetologists, Paediatricians with a special interest in diabetes, Diabetes Specialist Nurses) in limited and controlled settings where patients are attending for type 1 diabetes mellitus care, as part of strategies to optimise a patient's HbA1c levels and reduce the frequency of hypoglycaemic episodes
	Insulin Pumps – adults and children 12 years and older
1.2	The CCG will commission insulin pump therapy in accordance with the criteria specified in NICE TA151 for adults and children 12 years and older, which states: Continuous subcutaneous insulin infusion (CSII or 'insulin pump') therapy is recommended as a treatment option for adults and children 12 years and older with type 1 diabetes mellitus or non-type 1, non-type 2 diabetes caused primarily by (near-) absence of insulin production provided that:
1.2.1 **1.2.2**	• Attempts to achieve target haemoglobin A1c (HbA1c) levels with multiple daily injections (MDIs) result in the person experiencing disabling hypoglycaemia. For the purpose of this guidance, disabling hypoglycaemia is defined as the repeated and unpredictable occurrence of hypoglycaemia that result in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life; OR • HbA1c levels have remained high (that is, at 8.5% [69 mmol/mol] or above) on MDI therapy (including, if appropriate, the use of long-acting insulin analogues) despite a high level of care
	Insulin Pumps – Children under 12 years
1.3	The CCG will commission insulin pump therapy for children under 12 years when EITHER: ALL OF THE FOLLOWING CRITERIA ARE MET: • provision of an insulin pump concurs with the preference of the patient or parent(s) / guardian(s) and takes into account any preference that the patient may be able to express, AND

1.3.1 **1.3.2** **1.3.3** **1.3.4** **1.3.5** **1.3.6**	• multi-disciplinary teams planning to commence a patient on insulin pump therapy must ensure that the disadvantages of therapy have been discussed with the patient or guardian(s) and the patient or parent(s) / guardian(s) have expressed a continued wish to initiate insulin pump therapy, AND • the patient or parent(s) / guardian(s) must have demonstrated appropriate levels of competence to perform carbohydrate counting (e.g. level 3 carbohydrate counting such as DAFNE regimen; or have been judged by their specialist supervising clinician to have demonstrated an equivalent level of competence through the prior management of the patient's glycaemic control), blood glucose monitoring and the patient or parent(s) / guardian(s) must be able to interpret this data to competently adjust insulin doses, AND • the patient or parent(s) / guardian(s) must have performed frequent blood glucose self-monitoring (ONLY if the patient has previously received insulin therapy) at least 5 times daily (as described in NICE NG18) AND • the patient or parent(s) / guardian(s) must demonstrate a willingness to engage in all necessary training. OR • The patient has a definitive diagnosis of needle phobia. The diagnosis must have been made by a specialist with expertise in behavioural therapy and all therapeutic interventions to manage the phobia have failed.
1.4 **1.4.1** **1.4.2** **1.4.3**	At the point of device renewal (4 years after the issue of the device) all patients must show: 1. appropriate device use and compliance with associated testing regimens AND 2. a clearly documented achievement of targets for glycaemic control measures including: a) HbA1c levels b) rate and severity of hypoglycaemic and hyperglycaemic episodes (including episodes of DKA) c) Quality of Life measures (e.g. NICE referenced EQ-5D assessment and / or DQoL questionnaire) All targets must be agreed by the responsible specialist clinician. Children under the age of 12 who have been initiated on an insulin pump would be expected to undergo a trial of MDI therapy ONCE between the ages of 12 and 18. This trial must be conducted at the point after their twelfth birthday when their current pump warranty comes to an end. This is required to secure continued funding in accordance with NICE TA 151. The timing of such a trial will be agreed with the responsible clinician to suit the individual needs of the patient. Should the responsible specialist clinician believe a trial of MDI to be inappropriate, the basis for not conducting such a

1.4.4	trial must be clearly documented to enable continued funding of the insulin pump device. The CCG will not commission continuation of insulin pump treatment commenced in the private sector (self-funded) either in the UK or abroad. However, exceptions are permissible when NHS funded treatment would normally be made available to NHS patients within the terms detailed in this policy. The following statement(s) must apply: • the patient must have demonstrably satisfied the initiation criteria detailed in this policy *at the time of commencing* the self-funded insulin pump, as confirmed and documented by the specialist clinician through a review of the patient's medical history. • at the point of device renewal, the patient must satisfy the continuation eligibility criteria above and have previously satisfied the initiation criteria *at the time of commencing* the self-funded insulin pump.
2	**Scope and definitions**
2.1	This policy is based on the CCGs' Statement of Principles for Commissioning of Healthcare (version in force on the date on which this policy is adopted).
2.2	Type 1 diabetes mellitus is a chronic metabolic disorder caused by the destruction of insulin-producing cells in the pancreas that leads to an absolute lack of the hormone and subsequent loss of blood glucose control. Treatment of type 1 diabetes mellitus is by insulin therapy to achieve blood glucose control. Many patients can achieve blood glucose control through multiple daily injections of insulin (MDI) using a mixture of rapid-acting, short-acting, intermediate-acting and long-acting insulins. For those patients with type 1 diabetes mellitus who have difficulty controlling their blood glucose through MDI, insulin pump therapy provides an alternative treatment option. Type 2 diabetes mellitus is a chronic metabolic condition characterised by insulin resistance (that is, the body's inability to effectively use insulin) and insufficient pancreatic insulin production, resulting in high blood glucose levels (hyperglycaemia). Patients with type 2 diabetes mellitus may initially be managed with lifestyle and dietary changes alone, although due to the progressive nature of the disease many patients will require interventions with medicines including insulin as glycaemic control deteriorates. Insulin pumps are programmable devices with refillable reservoirs of short-acting insulin which deliver (pump) insulin subcutaneously through a sited cannula to provide a continuous infusion of insulin. The pump can be programmed to deliver a basal rate of insulin throughout the day, with higher infusion rates triggered by pushing a button at meal times. This may be as a bolus or delivered over a period of time. The pump can also deliver different basal rates of insulin at different times of the day and night.
2.3	The scope of this policy includes requests for insulin pumps for adults and children of any age with a confirmed diagnosis of type 1 or type 2 diabetes mellitus; or non-type 1, non-type 2 diabetes caused primarily by (near-) absence of insulin production (e.g. cystic fibrosis-related diabetes, post-

	pancreatic destruction, post-pancreatectomy diabetes) where these patients fulfil NICE TA151 criteria in every regard other than having type 1 diabetes.
2.4	The scope of this policy does not include the provision of insulin pumps for adults and children who do not have a confirmed diagnosis of diabetes mellitus or any other aspects of the management of type 1 and type 2 diabetes mellitus.
2.5	The CCG recognises that a patient may have certain features, such as: • having type 1; type 2 diabetes mellitus; or non-type 1, non-type 2 diabetes caused primarily by (near-) absence of insulin production • wishing to have a service provided for type 1; type 2 diabetes mellitus; or non-type 1, non-type 2 diabetes caused primarily by (near-) absence of insulin production • being advised that they are clinically suitable for an insulin pump; and • being distressed by having type 1; type 2 diabetes mellitus; or non-type 1, non-type 2 diabetes caused primarily by (near-) absence of insulin production This alone is not sufficient to meet the criteria specified in this commissioning policy. Such features place the patient within the group to whom this policy applies and do not make them exceptions to it.
2.6	The NICE technology appraisal guidance 151 does not recommend insulin pump therapy for patients with type 2 diabetes as a cost-effective use of NHS resource. On this basis the CCG will not routinely commission insulin pump therapy for patients with type 2 diabetes mellitus.
2.7	Terms and abbreviations used in this policy are explained and defined in Appendix 1. Throughout this policy any term is used with the meaning described in that appendix.
2.8	This policy references the guidance of The National Institute for Health and Care Excellence (NICE), in particularly TA151 (published in July 2008), which is mandatory, and NG17 and NG18 (both published in August 2015), which are not mandatory, and relate to adults and to children & young people respectively.
3	**Appropriate Healthcare**
3.1	The purpose of an insulin pump device is to reduce the variability of blood glucose levels in patients unable to achieve satisfactory control using MDI insulin. Improved control of blood glucose levels reduces the likelihood of short-term complications such as episodes of low blood glucose (hypoglycaemia) or high glucose (hyperglycaemia) leading to life-threatening emergencies such as diabetic ketoacidosis. The long-term microvascular and macrovascular complications of chronically elevated blood glucose levels include retinopathy, nephropathy, neuropathy and blindness, renal failure and foot ulceration respectively.

3.2	Due to the effects of insulin treatment and diabetic complications on a patient's quality of life, the CCG regards the provision of insulin pumps in accordance with the Principles of Appropriateness. The policy does not rely on the Principle of Appropriateness. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider the principle of appropriateness in the particular circumstances of the patient in question before confirming a decision to provide funding.
4	**Effective Healthcare**
4.1	The CCG does not call into question the effectiveness of insulin pump therapy in improving blood glucose control or the resultant prevention/delay in onset of diabetic complications afforded by improved blood glucose management. This policy does not therefore rely on the Principle of Effectiveness. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the purpose of the treatment is likely to be achieved in this patient without undue adverse effects before confirming a decision to provide funding.
5	**Cost-Effectiveness**
5.1	This policy relies on the Principle of Cost-Effectiveness. The CCG recognises the provision of insulin pump therapy to improve blood glucose control would not represent a cost-effective use of NHS resources in the following patient cohorts (based on the recommendations of NICE TA151): 1. those patients that can achieve satisfactory blood glucose control (defined as agreed targets made by the specialist clinician in conjunction with the patient) by administering multiple daily injections of insulin AND 2. all patients with type 2 diabetes mellitus NICE TA151 defines cost-effective uses of insulin pump therapy in adults and children 12 years and older reliant on: • raised baseline HbA1c (that is, at 8.5% [69 mmol/mol] or above) on MDI therapy (including, if appropriate, the use of long-acting insulin analogues) despite a high level of care prior to commencing insulin pump therapy or • increased episodes of disabling hypoglycaemia in patients attempting to achieve their target HbA1c levels with MDI therapy For the use of insulin pumps in place of MDI in children under 12 years, the CCG considers that the relative costs, expected clinical benefits and limitations of insulin pump therapy may vary from patient to patient. **There is insufficient evidence to define cost-effective use of insulin pumps in children under 12 years using thresholds for baseline HbA1c or frequency of hypoglycaemic episodes.** The strongest indicator of improved clinical outcomes in patients under 12 years relates to competence in the use of the pump device and treatment compliance.
6	**Ethics**

6.1	The CCG does not call into question the ethics of insulin pump therapy and therefore this policy does not rely on the Principle of Ethics. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the treatment is likely to raise ethical concerns in this patient before confirming a decision to provide funding.
7	**Affordability**
7.1	The CCG does not call into question the affordability of insulin pump therapy and therefore this policy does not rely on the Principle of Affordability. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the treatment is likely to be affordable in this patient before confirming a decision to provide funding.
8	**Exceptions**
8.1	The CCG will consider exceptions to this policy in accordance with the Policy for Considering Applications for Exceptionality to Commissioning Policies.
8.2	In the event of inconsistency, this policy will take precedence over any non-mandatory NICE guidance in driving decisions of this CCG. A circumstance in which a patient satisfies NICE guidance but does not satisfy the criteria in this policy does not amount to exceptionality.
9	**Force**
9.1	This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance relating to this intervention, or to alternative treatments for the same condition.
9.2	In the event of NICE guidance referenced in this policy being superseded by new NICE guidance, then: • If the new NICE guidance has mandatory status, then that NICE guidance will supersede this policy with effect from the date on which it becomes mandatory. • If the new NICE guidance does not have mandatory status, then the CCG will aspire to review and update this policy accordingly. However, until the CCG adopts a revised policy, this policy will remain in force and any references in it to NICE guidance will remain valid as far as the decisions of this CCG are concerned.
10	**References**
	1. National Institute for Health and Clinical Excellence (2008) Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus. Technology appraisal guideline 151 (TA151) accessed at https://www.nice.org.uk/guidance/ta151

	2. National Institute for Health and Care Excellence (2016) Type 1 diabetes in adults: diagnosis and management. NICE guideline (NG17) accessed at https://www.nice.org.uk/guidance/ng17 3. National Institute for Health and Care Excellence (2016) Diabetes (type 1 and type 2) in children and young people: diagnosis and management. NICE guideline (NG18) accessed at https://www.nice.org.uk/guidance/ng18
11	**Appendix 1 – Terms and abbreviations**
	CCG – Clinical Commissioning Group. MDI – Multiple daily injections. In this policy this refers to four or more daily injections of insulin. Diabetes mellitus – As defined by the World Health Organisation 2006 plasma glucose criteria (fasting plasma glucose ≥ 7.0mmol/l (126mg/dl) or 2–h plasma glucose ≥ 11.1mmol/l (200mg/dl).) NICE – National Institute for Health and Care Excellence TA151 – NICE technology appraisal guideline 151 (Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus). NG17 – NICE guideline 17 (Type 1 diabetes in adults: diagnosis and management). NG18 – NICE guideline 18 (Diabetes [type 1 and type 2] in children and young people: diagnosis and management). Adult – A person over the age of 18. Children – To align with TA151 and for the purposes of this policy all people under the age of 18 are referred to as children. Young people - A person between the ages of 12 and 18 years. (However, the separate definitions for children and young people are not stated in NG18 or TA151). HbA1c - Glycated haemoglobin measured using methods that have been calibrated according to International Federation of Clinical Chemistry (IFCC) standardisation. Disabling hypoglycaemia – defined by TA 151 as the repeated and unpredictable occurrence of hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life. DKA – Diabetic Ketoacidosis. EQ-5D – Validated Quality of Life measure developed by EuroQol and referenced by NICE.

	DQoL – Diabetes Quality of Life measure. A validated tool designed by the Diabetes Control and Complications Research Group.

Date of adoption
Date for review

Policy for managing low back pain- spinal injections and radiofrequency denervation.		
	Version Number:	**Changes Made:**
Version of: August 2018	V0.4	- Policy title amended to include the word “low” to add clarity following patient engagement. - OPCS/ ICD codes added
Version of: April 2018	V 0.3	Scope of the policy clarified, including the removal of pathway diagrams, and policy content and title refined to reflect the policy is limited to the use of non-surgical invasive treatments for the management of low back pain.
Version of: February 2018	V0.2	The following changes were made following consideration of the stage 3 feedback: - Scope clarified to make it explicit it applies to patients over 16 years only. - 8.2.1- wording regarding the number of injections commissioned altered to align with the wording at 8.2.3.
Original Draft: November 2017	V0.1	Initial draft prepared in line with the Pennine policy and a meeting with Anne Greenwood, Pennine policy lead.

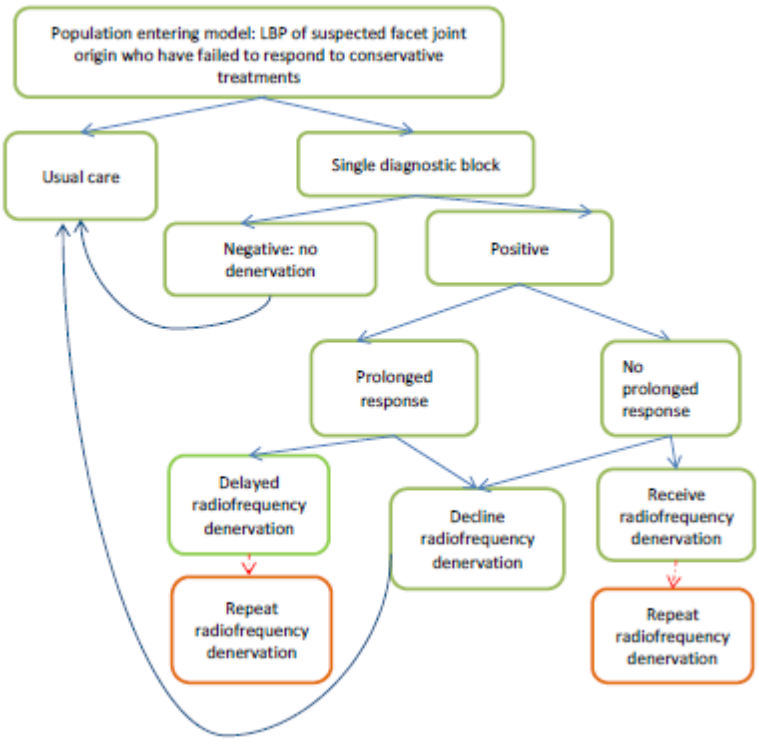
Lancashire and South Cumbria Clinical Commissioning Groups (CCGs)

Policies for the Commissioning of Healthcare

Policy for Managing Low Back Pain- Spinal Injections and Radiofrequency Denervation

1	**Introduction**
1.1	This document is part of a suite of policies that the CCG uses to drive its commissioning of healthcare. Each policy in that suite is a separate public document in its own right, but will be applied with reference to other policies in that suite.
1.2	This policy is based on the CCGs Statement of Principles for Commissioning of Healthcare (version in force on the date on which this policy is adopted).
2	**Policy**
2.1	**Spinal injections** Invasive, non-surgical interventions and treatments for low back pain and sciatica must be considered in line with NICE NG59 published 30.11.2016.
2.1.1	**Radicular pain** An initial assessment should be undertaken in line with NICE guidance, including the consideration of red flags and a validated tool and the use of non-pharmacological & pharmacological interventions, including self-management, should be **optimised prior to injection therapy.** **Eligibility criteria:** When all the following criteria are satisfied the CCG will commission a maximum of two spinal facet joint and caudal injections prior to Consultant referral for further management. A maximum of two further therapeutic injections will be funded within any individual treatment cycle prior to patient discharge or surgical referral: **a)** Selective nerve root blocks or DRG block can be used for diagnostic purposes in people with **acute and severe sciatica**. **b)** Epidural injections (nerve root block, dorsal root ganglion block, DRG) with local anaesthetics and steroids for radicular pain (neck & back) will only be funded in people with **acute and severe sciatica.** **c)** Injections must be part of a multimodal, multidisciplinary management plan (injection + medications + physiotherapy +/- CBT)
2.1.2	**Non-specific low back pain (NSLBP)** Spinal injections for managing NSLBP should not be offered, in line with NICE Guidance, NG59.

2.1.3	**Specific low back pain** An initial assessment should be undertaken in line with NICE guidance, including the consideration of red flags and a validated tool and the use of non-pharmacological & pharmacological interventions, including self-management, should be **optimised prior to injection therapy.** There are multiple possible causes for "Specific low back pain" and consequently the following evidence-based injections could be considered in the following circumstances: ✓ **For Myofascial pain**: o Trigger points injection and if positive Botox injection ✓ **Failed back surgery (epidural scar tissue**) o Release of Epidural adhesions (Adhesiolysis) o Spinal cord stimulation ✓ **Sacroiliac joint (SIJ) stress/ osteoarthritis (after diagnostic block)** o **Radiofrequency Lesion (RFL) denervation** of SIJ (after positive diagnostic block) ✓ **Facet joints pain (after positive medial branch block)** o Facet Joints injection (FJI) o **RFL denervation** of lumbar facets (after positive block) ✓ **Fractured vertebra (osteoporosis or cancer)** o Percutaneous Vertebroplasty or Kyphoplasty ✓ **Discogenic pain (positive discography)** o Percutaneous discectomy (RFL or Mechanical) ✓ **Lumbar sympathetic nerves pathology (after diagnostic sympathetic block)** o Lumbar sympathetic ablation (phenol, alcohol or RFL) **Eligibility criteria:** • Patient assessment & injection must be performed by a clinician trained in back pain assessment, diagnosis and management as part of a full MDT management plan approach. • The CCG will fund a maximum number of two caudal epidurals for specific low back pain before Consultant referral for further management • A maximum of two further therapeutic epidural injections will be funded within any individual treatment cycle prior to patient discharge or surgical referral.
2.2 **2.2.1**	**Radiofrequency denervation** **Consider referral for assessment for radiofrequency denervation for people with chronic low back pain when:** a. Non-surgical treatment has not worked for them **AND** b. the main source of pain is thought to come from structures supplied by the medial branch nerve (positive diagnostic medial branch block) **AND** c. they have moderate or severe levels of localised back pain (rated as 5 or more on a visual analogue scale, or equivalent) at the time of referral'

2.2.2	The CCG will commission radiofrequency denervation in the following circumstances: a. In people with chronic low back pain following a positive response to a diagnostic medial branch block b. Current NICE guidance and The National Low Back and Radicular Pain Pathway 2017 have been utilised in the development of this guidance, however clinical experience and best practice has been also been considered. Given nerves generally recover after 6 to 9 months following the denervation procedure meaning the pain could return, the CCG will commission repeat radiofrequency denervation after a period of 6 months, provided the discharge criteria set out in section 8.3.3 below are met.
2.2.3	The following patient discharge criteria must be adhered to by all clinicians following radiofrequency denervation treatment: • Patients must be discharged from the service post denervation if pain relief is >50% for a period of >4 months. • Should a new referral be required this must be accompanied by completion of a new assessment within primary care. Pathway as follows: **Figure 1: Pathway in the model**  https://docs.wixstatic.com/ugd/dd7c8a_caf17c305a5f4321a6fca249dea75ebe.pdf
3	**Scope and definitions**
3.1	The scope of this policy includes the use of spinal injections and radiofrequency denervation for the management of low back pain in patients

	over the age of 16 years.
3.2	The scope of this policy does not include the specific management of back pain related to red flags or the management of low back pain related to the following conditions: • Infection • Trauma (e.g. fractured spine which may need vertebroplasty or kyphoplasty as approved by NICE) https://www.nice.org.uk/guidance/ta279 • Inflammatory disease such as spondyloarthritis https://www.nice.org.uk/guidance/ng59/chapter/Recommendations#assessment-of-low-back-pain-and-sciatica • The evaluation of people with sciatica with progressive neurological deficit or cauda equina • Scoliosis **Red Flags** Consider specifically if there are features of the conditions below. If serious underlying pathology is suspected refer to the relevant NICE guidance: • Spondyloarthritis http://www.nice.org.uk/guidance/ng65 • Spinal injury http://www.nice.org.uk/guidance/ng41 • Metastatic spinal cord compression http://www.nice.org.uk/guidance/cg75 • Suspected cancer http://www.nice.org.uk/guidance/ng12
3.3	The CCG recognises that a patient may have certain features, such as • having back pain, • wishing to have a service provided for back pain, • being advised that they are clinically suitable for spinal injections, and • being distressed by their back pain, and by the fact that that they may not meet the criteria specified in this commissioning policy. Such features place the patient within the group to whom this policy applies and do not make them exceptions to it.
3.4	There are three groupings of pathologies that commonly affect the lumbar spine and cause back pain for which injections have been considered. These groups however, are very different in their response to injection therapy. Before treatment, patients need adequate assessment within a multi-disciplinary team and management approach to make a diagnosis or diagnoses. Injections could be part of the diagnosis process (diagnostic block). For the purpose of this policy the CCG defines the groups as follows: **A) Radicular pain** - Patients with nerve root compression irritation and/or inflammation. Patients typically present with predominantly leg pain or sciatica. The two most common causes of radicular pain are prolapsed (herniated)

	intervertebral disc and spinal canal stenosis. Patients should be managed on an explicit care pathway with explicit review and decision points. Injection therapy for radicular pain in a carefully selected patient is an appropriate procedure and is therefore funded in certain circumstances. See section 8.2.1 for eligibility criteria. **B) Non-specific low back pain (NSLBP)** – is low back pain not attributable to a specific pathology/ cause. It is not associated with potentially serious causes (e.g. infection, tumour, fracture, structural deformity, inflammatory disorder, radicular syndrome, or cauda equina syndrome). The management of non-specific low back pain represents a challenge in health care provision. NSLBP is also known as low back pain, mechanical, musculoskeletal or simple low back pain (NG59) Injection therapy is not an appropriate procedure for NSLBP, as advised by NICE NG59, and is therefore not funded. **(C) Specific low back pain** - is back pain attributed to a specific pathology or cause. Specific back pain can have multiple causes including: Myofascial pain, specific disc bulge, failed back surgery, fracture vertebra, inflammation /stress of Sacroiliac or facet joints (after positive diagnostic block) or lumbar sympathetic nerves pathology. Injection therapy for specific low back pain in carefully selected patients within a multi-disciplinary team management approach is an appropriate procedure and is therefore funded in certain circumstances. See section 8.2.3 for eligibility criteria.
3.5	Relevant evidence and guidelines have been reviewed including taking into account the recommendations of: • NICE quality standard published 27July 2017 https://nice.org.uk/guidance/qs155 • NICE guidance published 30th November 2016 https://www.nice.org.uk/guidance/ng59 • NHSE National Pathway of Care for Low Back Pain & Radicular Pain December 2014 http://rcc-uk.org/wp-content/uploads/2015/01/Pathfinder-Low-back-and-Radicular-Pain.pdf • Royal College of Surgeons Commissioning Guide: Low back pain 2013 and NHSE Guide to Commissioners of Spinal Services January 2013 • NHS RightCare https://www.england.nhs.uk/rightcare/
4	**Appropriate Healthcare**
4.1	Spinal facet joint and epidural injections are invasive treatments that are used in two ways:

	• First (**Diagnostic**): Selective nerve root block can be used to diagnose the source of radicular back pain. Medial branch block is recognised as a diagnostic tool to diagnose the source of facet joints pain. • Second (**Therapeutic**): spinal facet joint injections and epidural injections are used as a treatment to relieve both radicular and specific pain low back pain.
4.2	The CCG regards the achievement of this purpose as according with the Principle of Appropriateness. Therefore, this policy does not rely on the principle of appropriateness. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider the principle of appropriateness in the particular circumstances of the patient in question before confirming a decision to provide funding.
5	**Effective Healthcare**
5.1	The following policy criteria rely on the principle of effectiveness: • The criterion at section 8.2.2 relating to NSLBP as NICE NG59 states there was no consistent good quality evidence to recommend the use of spinal injections for the management of non-specific low back pain. There was minimal evidence of benefit from injections, and reason to believe that there was a risk of harm, even if rare.
6	**Cost Effectiveness**
6.1	The CCG does not call into question the cost-effectiveness of spinal facet joint and caudal injections and therefore this policy does not rely on the Principle of Cost-Effectiveness. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the treatment is likely to be Cost Effective in this patient before confirming a decision to provide funding.
7	**Ethics**
7.1	The CCG does not call into question the ethics of spinal facet joint and caudal injections and therefore this policy does not rely on the Principle of Ethics. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the treatment is likely to raise ethical concerns in this patient before confirming a decision to provide funding.
8	**Affordability**
8.1	The CCG does not call into question the affordability of spinal facet joint and caudal injections and therefore this policy does not rely on the Principle of Affordability. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the treatment is likely to be affordable in this patient before confirming a decision to provide funding.
9	**Exceptions**

9.1	The CCG will consider exceptions to this policy in accordance with the Policy for Considering Applications for Exceptionality to Commissioning Policies.
9.2	In the event of inconsistency, this policy will take precedence over any non-mandatory NICE guidance in driving decisions of this CCG. A circumstance in which a patient satisfies NICE guidance but does not satisfy the criteria in this policy does not amount to exceptionality.
10	**Force**
10.1	This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance relating to this intervention, or to alternative treatments for the same condition.
10.2	In the event of NICE guidance referenced in this policy being superseded by new NICE guidance, then: • If the new NICE guidance has mandatory status, then that NICE guidance will supersede this policy with effect from the date on which it becomes mandatory. • If the new NICE guidance does not have mandatory status, then the CCG will aspire to review and update this policy accordingly. However, until the CCG adopts a revised policy, this policy will remain in force and any references in it to NICE guidance will remain valid as far as the decisions of this CCG are concerned.
11	**References**
	NHS England (2013) Guide to the Commissioners of Spinal Services http://www.nationalspinaltaskforce.co.uk/pdfs/NHSSpinalReport_vis7%2030.01.13.pdf Royal College of Surgeons Commissioning Guide: Low back pain 2013 http://www.rcseng.ac.uk/healthcare-bodies/docs/commissioning-guides-boa/lower-back-paincommissioning-guide NHS Guidelines CG 88 (May 2009) Low Back Pain in Adults: Early Management https://www.nice.org.uk/Guidance/CG88 NHS England National Pathfinder Projects (December 2014) National Pathway of Care for Low Back and Radicular Pain *(Report of the Clinical Group)* http://www.rcseng.ac.uk/healthcare-bodies/docs/pathfinder-low-back-and-radicular-pain NHS Wiltshire CCG "Managing Back Pain - Spinal Facet Joint and Epidural Injections Policy" (July 2014) http://www.wiltshireccg.nhs.uk/wp-content/uploads/2013/12/Managing-Back-Pain-Spinal-Facet-Joint-and-Epidural-Injections-Policy-AMENDED.pdf NHS Shropshire CCG "PROCEDURES OF LIMITED CLINICAL VALUE POLICY" (September 2015)

	http://www.shropshireccg.nhs.uk/download.cfm?doc=docm93jijm4n2001.pdf&ver=12190 NHS Guidelines NG59 (November 2016) Low back pain and sciatica in over 16s assessment and management https://www.nice.org.uk/guidance/ng59/resources/low-back-pain-and-sciatica-in-over-16sassessment-and-management-1837521693637

Appendix 1: Associated OPCS codes

The codes applicable to this policy are:

OPCS codes
A522, A528, A529, A573, A574, A575, A577, V485, V486, V487, V488, V544, W903, X375, X382

Date of adoption
Date for review

Policy for the Provision of Continuous Glucose Monitoring and Flash Glucose Monitoring to patients with Diabetes Mellitus		
	Version No.	**Changes Made**
Version of July 2018	V 0.5	Changes made to the policy following patient engagement including: - the inclusion of treatment for patients with non-type 2 diabetes caused by the absence of insulin production; - clear eligibility criteria for patients who initiated treatment privately - change to the threshold related to carbohydrate counting.
Version of May 2018	V 0.4	Clarity provided that CGM and flash will not be funded simultaneously. Policy criteria moved to the beginning of the policy.
Version of: 01.03.2018	V 0.3	Amendments made to the policy following review by the Care Professionals Board (CPB): - Clarification added to the continuation criteria for CGM in hyperglycaemic patients. - Wording for CGM/flash and the clinicians who can provide the devices aligned.
Version of: 16.02.2018	V 0.2	Amendments made to the policy in line with discussions at the CPDIG following the stage 3 review
Version of: 15.01.2018	V0.1	Stand-alone glucose monitoring device policy drafted in line with the directive of the CPDIG in October and December 2017.

Lancashire and South Cumbria Clinical Commissioning Groups (CCGs)

Policies for the Commissioning of Healthcare

Policy for the Provision of Continuous Glucose Monitoring and Flash Glucose Monitoring to patients with Diabetes Mellitus.

	This document is part of a suite of policies that the CCG uses to drive its commissioning of healthcare. Each policy in that suite is a separate public document in its own right but will be applied with reference to other policies in that suite.
1	**Policy Criteria**
1.1	To be eligible for funding for a device under the provisions of this policy patients (or their parent(s) / guardian(s)) with type 1 diabetes mellitus or non-type 1, non-type 2 diabetes caused primarily by (near-) absence of insulin production must meet the device specific requirements set out at section 1.2 or 1.3 and: a) have been informed of the advantages and disadvantages of continuous/flash glucose monitoring and expressed a continued wish to initiate continuous/flash glucose monitoring. AND b) have demonstrated appropriate levels of competence to perform carbohydrate counting (e.g level 3 carbohydrate counting such as DAFNE regimen; or have been judged by their specialist supervising clinician to have demonstrated an equivalent level of competence through the prior management of the patient's glycaemic control), blood glucose monitoring and to interpret this data to competently adjust insulin doses. AND c) demonstrate a willingness to engage in all necessary training regarding the optimal use of continuous/flash glucose monitoring and commit to ongoing regular follow-up and monitoring (including remote follow-up where this is offered) AND EITHER d) in the case of flash glucose monitoring devices, be willing to commit to using the device daily including performing scans at least every 8 hours to provide a 24-hour ambulatory glucose profile; and utilising device readings to inform self-management OR e) in the case of continuous glucose monitoring devices, be willing to commit to using it at least 70% of the time or a minimum of 5 days per week and to calibrate it as needed
1.2	**Continuous Glucose Monitoring**
1.2.1	Continuous glucose monitoring must be initiated and continually supplied / prescribed by specialist clinicians (Diabetologists, Paediatricians with a special interest in diabetes, GPs with a special interest in Diabetes, Diabetes Specialist Nurses) in limited and controlled settings where patients are attending specialist diabetes

	mellitus care, as part of strategies to optimise a patient's HbA1c levels and reduce the frequency of hypoglycaemic episodes.
1.2.2	The CCG will only commission continuous glucose monitoring devices with alarms in patients with type 1 diabetes mellitus or non-type 1, non-type 2 diabetes caused primarily by (near-) absence of insulin production who fulfil the requirements of section 1.1 and who MEET ONE OR MORE OF THE FOLLOWING CRITERIA despite optimised use of insulin therapy and conventional blood glucose monitoring: 1. complete loss of awareness of hypoglycaemia (as indicated by a maximal score on the Gold or Clarke scales) OR 2. loss of awareness of hypoglycaemia (indicated by a score of more than 4 on the Gold or Clarke scales) accompanied by: i. adverse consequences (seizures or anxiety) or ii. frequent (more than 2 episodes per week) asymptomatic hypoglycaemia OR 3. have an inability to recognise, or communicate about, symptoms of hypoglycaemia (for example because of cognitive or neurological disabilities). OR 4. have experienced more than 1 episode a year of severe hypoglycaemia with no obviously preventable precipitating cause OR 5. have an extreme fear of hypoglycaemia (only in patients eligible for a flash glucose monitoring device who intensively monitor due to extreme fear of hypoglycaemia and who prefer to use continuous glucose monitoring) OR 6. have hyperglycaemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day *NB for children and young people, consent; commitment to use the device; and demonstration of competence may be the responsibility of the parent or guardian depending on the child or young person's level of understanding.*
1.2.3	To secure continued funding of continuous glucose monitoring with alarms patients must show: 1. appropriate device use and compliance (as demonstrated by a minimum of 70% use or 5 days wear per week) at **1 month** and at **any subsequent review**. 2. a clearly documented achievement of targets for glycaemic control measures at **3 months** and at **any subsequent review** including: a) rate and severity of hypoglycaemia OR b) quality of life measures (e.g. NICE referenced EQ-5D assessment and / or DQoL questionnaire), hypoglycaemia unawareness (Clarke or Gold score) or fear of hypoglycaemia OR

	c) HbA1c (an improvement of 5mmol/mol [0.5%] from baseline HbA1c is required if HbA1c was more than 59 mmol/mol [7.5%] at initiation of continuous glucose monitoring) ***** * For adult patients with a HbA1c of 75 mmol/mol (9%) or higher at the initiation of continuous glucose monitoring, continued funding will be secured if at the **6-month review** and at **any subsequent review:** - HbA1c has been reduced to 53 mmol/mol (7%) or below and/or - there has been a fall in HbA1c of 27 mmol/mol (2.5%) or more from their baseline HbA1c All targets must be agreed by a responsible specialist clinician.
1.3	**Flash Glucose Monitoring**
1.3.1	Flash glucose monitoring must be initiated and continually supplied / prescribed by specialist clinicians (Diabetologists, Paediatricians with a special interest in diabetes, GPs with a special interest in Diabetes, Diabetes Specialist Nurses) in limited and controlled settings where patients are attending for type 1 diabetes mellitus care. Clinicians providing flash glucose monitoring to patients must commit to the supply of audit data as outlined by the RMOC position statement until directed by the RMOC or appropriate commissioner to cease collection of audit data.
1.3.2	The CCG will only commission flash glucose monitoring devices in patients with type 1 diabetes mellitus or non-type 1, non-type 2 diabetes caused primarily by (near-) absence of insulin production who are aged 4 years and above, use multiple daily injections or insulin pump therapy, have been assessed by a specialist clinician, fulfil the requirements of section 1.1 and MEET ONE OR MORE OF THE FOLLOWING CRITERIA: 1. patients who undertake intensive monitoring for an expert accepted clinical need where the use of flash glucose monitoring would result in a reduction in finger prick testing of ≥ 8 times daily. This includes those patients who undertake intensive monitoring due to an extreme fear of hypoglycaemia. OR 2. children who require third parties to carry out monitoring and where conventional blood testing is not possible. This includes children who are unable to test as frequently as clinically appropriate, once all other clinical options have been evaluated. OR 3. patients who meet the current adult NICE criteria for insulin pump therapy (HbA1c >8.5% [69.4mmol/mol] or disabling hypoglycaemia as described in NICE TA151) AND a specialist clinician considers insulin pump therapy inappropriate; or the patient has been unable to continually use an insulin pump due to intolerance or lack of compliance.
1.3.3	To secure continued funding of the flash glucose device sensor patients must demonstrate:

	1. regular use of the flash glucose device at **1 month** and at **any subsequent review** with the specialist clinician (defined as performing scans **at least every 8 hours to provide a 24-hour ambulatory glucose profile** and **demonstrating evidence of device use in self-management**) 2. a clearly documented achievement of targets for glycaemic control measures or improvements in fear / anxieties related to fingerprick testing **every 6 months** defined by an improvement in Quality of Life measures (e.g. NICE referenced EQ-5D assessment and / or DQoL questionnaire) and one or more of the following: a. reduction in the rate of severe hypoglycaemia or hyperglycaemic episodes (including diabetic ketoacidosis) b. reduction in frequency of non-severe hypoglycaemia by more than 1 episode per week c. HbA1c reduction of 5mmol/mol [0.5%] from the baseline HbA1c within 6 months d. reduction in the rate of hospital admissions related to diabetic complications e. significant reduction in testing strip usage (more than 200 test strips per month) f. improvement in anxiety / fear using validated rating scales e.g. Hypoglycaemia Fear Survey-II (HSF-II) Where the above criteria are not met, flash glucose monitoring should be discontinued, and an alternative method of monitoring used.
1.4.1	The CCG will not commission continuation of continuous glucose monitoring or flash glucose monitoring commenced in the private sector (self-funded) either in the UK or abroad. However, exceptions are permissible when NHS funded treatment would normally be made available to NHS patients within the terms detailed in this policy. The following statement(s) must apply: • the patient must have demonstrably satisfied the initiation criteria detailed in this policy *at the time of commencing* the self-funded continuous glucose monitoring or flash glucose monitoring device, as confirmed and documented by the specialist clinician through a review of the patient's medical history. • at the point of device renewal, the patient must satisfy the continuation eligibility criteria above and have previously satisfied the initiation criteria *at the time of commencing* the continuous glucose monitoring or flash glucose monitoring device.
1.4.2	For insulin pump patients unable to achieve targets for glycaemic control measures as defined by the current local insulin pump policy, the decision to discontinue the insulin pump; or trial an insulin pump with integrated continuous glucose monitoring (where insulin pump patients are not already using continuous glucose monitoring); or trial a combination of insulin pump and flash glucose monitoring device; should be made by the responsible specialist clinician in conjunction with the patient. Combination continuous glucose monitoring and flash glucose monitoring will not be routinely commissioned by the CCG.

	Continuous glucose monitoring or flash glucose monitoring should only be continued in patients if they demonstrate the additional benefits defined in policy sections 1.2.3 and 1.3.3 respectively.
1.5	Neither the NICE clinical guidelines or the RMOC position statement provide guidance recommending continuous glucose monitoring or flash glucose monitoring for patients with type 2 diabetes as a cost-effective use of NHS resource. On this basis, the CCG will not commission continuous glucose monitoring or flash glucose monitoring in patients with type 2 diabetes mellitus.
2	**Scope and definitions**
2.1	This policy is based on the CCGs' Statement of Principles for Commissioning of Healthcare (version in force on the date on which this policy is adopted).
2.2	Type 1 diabetes mellitus is a chronic metabolic disorder caused by the destruction of insulin-producing cells in the pancreas that leads to an absolute lack of the hormone and subsequent loss of blood glucose control. Treatment of type 1 diabetes mellitus is by insulin therapy to achieve blood glucose control. Type 2 diabetes mellitus is a chronic metabolic condition characterised by insulin resistance (that is, the body's inability to effectively use insulin) and insufficient pancreatic insulin production, resulting in high blood glucose levels (hyperglycaemia). Patients with type 2 diabetes mellitus may initially be managed with lifestyle and dietary changes alone, although due to the progressive nature of the disease many patients will require interventions with medicines including insulin as glycaemic control deteriorates. To help maintain control of blood glucose levels, NICE guidelines recommends that type 1 patients self-monitor their blood glucose levels between 4 and 10 times a day. NICE guidelines do not recommend routine self-blood glucose monitoring in type 2 patients, except in patients using medicines which may cause hypoglycaemia (e.g. sulphonylureas and insulins). Currently most patients self-monitor blood glucose by applying a drop of blood to a testing strip. This strip is then inserted into a meter to display a blood glucose level. For those patients who are not satisfactorily managed with self-monitored finger prick blood-glucose testing, continuous glucose monitoring and flash glucose monitoring are alternative glucose monitoring methods. Continuous glucose monitoring systems use a sensor to continuously measure interstitial fluid glucose levels and automatically transmit readings to a receiver every 5 minutes. Continuous glucose monitoring devices may be fitted with alarms to alert patients when blood glucose levels are too high or low and can be integrated into continuous subcutaneous insulin infusion devices (insulin pumps) to allow real time adjustment of insulin doses or suspend insulin delivery following a low-glucose warning. Flash glucose monitoring systems use a sensor to measure interstitial fluid glucose levels every minute and stores glucose levels at 15-minute intervals for 8 hours. Glucose levels can be seen at any time by scanning a reader over the sensor. The

	sensor must be scanned at least every 8 hours to provide a full 24 hours of data. The device does not provide a hypoglycaemia alarm; the sensor must be scanned to detect when the glucose level is too high or too low.
2.3	The scope of this policy includes requests for continuous glucose monitoring and flash glucose monitoring devices for adults and children of any age with a confirmed diagnosis of type 1, type 2 diabetes mellitus or non-type 1, non-type 2 diabetes patients caused primarily by (near-) absence of insulin production (e.g. cystic fibrosis-related diabetes, post-pancreatic destruction, post-pancreatectomy diabetes) where these patients fulfil NICE TA151 criteria in every regard other than having type 1 diabetes.
2.4	The scope of this policy does not include the provision of continuous glucose monitoring and flash glucose monitoring devices for adults and children who do not have a confirmed diagnosis of diabetes mellitus or any other aspects of the management of type 1 or type 2 diabetes mellitus or cystic fibrosis-related diabetes.
2.5	The CCG recognises that a patient may have certain features, such as: • having type 1 or 2 diabetes mellitus or non-type 1, non-type 2 diabetes patients caused primarily by (near-) absence of insulin production; • wishing to have a service provided for type 1 or 2 diabetes mellitus or non-type 1, non-type 2 diabetes patients caused primarily by (near-) absence of insulin production; • being advised that they are clinically suitable for a continuous glucose monitoring or flash glucose monitoring device; and • being distressed by having type 1 or 2 diabetes mellitus or non-type 1, non-type 2 diabetes patients caused primarily by (near-) absence of insulin production. This alone is not sufficient to meet the criteria specified in this commissioning policy. Such features place the patient within the group to whom this policy applies and do not make them exceptions to it.
2.6	Terms and abbreviations used in this policy are explained and defined in Appendix 1. Throughout this policy any term is used with the meaning described in that appendix.
2.7	This policy references the advice of the Regional Medicines Optimisation Committee (RMOC) (published in October 2017) and The National Institute for Health and Care Excellence (NICE), in particularly NG17 and NG18 (both published in August 2015), which relates to adults and to children & young people respectively. Appendix 2 contains statements from the relevant guidelines to support recommendations within the policy.
3	**Appropriate Healthcare**
3.1	The purpose of continuous glucose monitoring and flash glucose monitoring devices are to reduce the variability of blood glucose levels. This is achieved by enabling patients to intervene quicker (than would have been possible with finger prick glucose testing) when blood glucose levels deviate from euglycaemia due to more frequent testing and availability of blood glucose data. Improved control of blood glucose

	levels reduces the likelihood of short-term complications such as episodes of low blood glucose (hypoglycaemia) or life-threatening emergencies such as diabetic ketoacidosis (a consequence of high blood glucose levels).
3.2	The CCG regards the achievement of this purpose of continuous glucose monitoring and flash glucose monitoring as according with the Principle of Appropriateness. Therefore this policy does not rely on the principle of appropriateness. Nevertheless if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider the Principle of Appropriateness in the particular circumstances of the patient in question before confirming a decision to provide funding.
4	**Effective Healthcare**
4.1	The CCG does not call into question the effectiveness of continuous glucose monitoring or flash glucose monitoring and therefore this policy does not rely on the Principle of Effectiveness. Nevertheless if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the purpose of the treatment is likely to be achieved in this patient without undue adverse effects before confirming a decision to provide funding.
5	**Cost Effectiveness**
5.1	This policy relies on the Principle of Cost-Effectiveness. The CCG considers that in most patients able to achieve their agreed HbA1c target without disabling hypoglycaemia using alternative methods of self-monitoring of blood glucose, the use of continuous glucose monitoring and flash glucose monitoring to improve blood glucose control would not represent a cost-effective use of NHS resources. In determining the circumstances under which continuous glucose monitoring and flash glucose monitoring are cost-effective, the CCGs have referenced the guidance of the RMOC and NICE clinical guidelines NG17, NG18 and NG28 which relate to adults with type 1 diabetes mellitus; children and young people with type 1 and 2 diabetes mellitus; and adults with type 2 diabetes mellitus respectively.
6	**Ethics**
6.1	The CCG does not call into question the ethics of continuous glucose monitoring or flash glucose monitoring and therefore this policy does not rely on the Principle of Ethics. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the treatment is likely to raise ethical concerns in this patient before confirming a decision to provide funding.
7	**Affordability**
7.1	The CCG does not call into question the affordability of continuous glucose monitoring or flash glucose monitoring and therefore this policy does not rely on the Principle of Affordability. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider

	whether the treatment is likely to be affordable in this patient before confirming a decision to provide funding.
8	**Exceptions**
8.1	The CCG will consider exceptions to this policy in accordance with the Policy for Considering Applications for Exceptionality to Commissioning Policies.
8.2	In the event of inconsistency, this policy will take precedence over any non-mandatory NICE guidelines in driving decisions of this CCG. A circumstance in which a patient satisfies NICE guidelines but does not satisfy the criteria in this policy does not amount to exceptionality.
9	**Force**
9.1	This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance relating to this intervention, or to alternative treatments for the same condition.
9.2	In the event of NICE guidance referenced in this policy being superseded by new NICE guidance, then: • If the new NICE guidance has mandatory status, then that NICE guidance will supersede this policy with effect from the date on which it becomes mandatory. • If the new NICE guidance does not have mandatory status, then the CCG will aspire to review and update this policy accordingly. However, until the CCG adopts a revised policy, this policy will remain in force and any references in it to NICE guidance will remain valid as far as the decisions of this CCG are concerned.

10	**References**
	1. National Institute for Health and Clinical Excellence (2008) Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus. Technology appraisal guideline 151 (TA151). Available at https://www.nice.org.uk/guidance/ta151 2. National Institute for Health and Care Excellence (2016) Type 1 diabetes in adults: diagnosis and management. NICE guideline (NG17). Available at https://www.nice.org.uk/guidance/ng17 3. National Institute for Health and Care Excellence (2016) Diabetes (type 1 and type 2) in children and young people: diagnosis and management. NICE guideline (NG18). Available at https://www.nice.org.uk/guidance/ng18 4. National Institute for Health and Care Excellence (2015) Type 2 diabetes in adults: management. NICE guideline (NG28). Available at https://www.nice.org.uk/guidance/ng28 5. Regional Medicines Optimisation Committee (2017) Flash Glucose Monitoring Systems Position Statement. Available at https://www.sps.nhs.uk/wp-content/uploads/2017/11/Flash-Glucose-monitoring-System-RMOC-Statement-final-2.pdf 6. NICE Medtech Innovation Briefing [MIB 110]: FreeStyle Libre® for glucose monitoring NICE July 2017. Available at https://www.nice.org.uk/advice/mib110

	7. ABCD Type 1 Diabetes Clinical Collaborative: Information to help a formulary case for Freestyle Libre System October 2017. Available at https://abcd.care/getting-freestyle-libre-your-formulary 8. ACDC (2017) A Practical Approach to the Management of Continuous Glucose Monitoring (CGM) / Real-Time Flash Glucose Scanning (FGS) in Type 1 Diabetes Mellitus in Children and Young People Under 18 Years. Available at https://www.bsped.org.uk/clinical/docs/CGM-FGS-ACDC-Guideline.pdf 9. Diabetes UK (2017) Diabetes UK Consensus Guideline for Flash Glucose Monitoring. Available at https://www.diabetes.org.uk/resources-s3/2017-09/1190_Flash%20glucose%20monitoring%20guideline_SB_V9%5B4%5D.pdf
11	**Appendix 1 – Terms and abbreviations**
	CCG – Clinical Commissioning Group. NICE – National Institute for Health and Care Excellence RMOC – Regional Medicines Optimisation Committee Diabetes mellitus – As defined by the World Health Organisation 2006 plasma glucose criteria (fasting plasma glucose ≥ 7.0mmol/l (126mg/dl) or 2–h plasma glucose ≥ 11.1mmol/l (200mg/dl).) Euglycaemia – Normal concentration of glucose in the blood within an optimal range of 90–130 mg/dl HbA1c - Glycated haemoglobin measured using methods that have been calibrated according to International Federation of Clinical Chemistry (IFCC) standardisation. MDI – Multiple daily injections. In this policy this refers to four or more daily injections of insulin. NG17 – NICE guideline 17 (Type 1 diabetes in adults: diagnosis and management). NG18 – NICE guideline 18 (Diabetes [type 1 and type 2] in children and young people: diagnosis and management). NG28 – NICE guideline 28 (Type 2 diabetes in adults: management). TA151 – NICE technology appraisal guideline 151 (Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus). Adult – A person over the age of 18 years. Children and young people – Covers people under the age of 18 years as defined by NG18. Children may be defined as people under the age of 12 years and young people defined as people between the ages of 12 and 18 years. (However, the separate definitions for children and young people are not stated in NG18 or TA151). DAFNE – Dose Adjustment For Normal Eating (regimen for patient self-management).

	Gold Score – A method used to assess impairment of awareness of hypoglycaemia. This comprises a single question “do you know when your hypos are commencing” and a 7-point Likert scale for responses ranging from 1 (always aware) to 7 (never aware). A score of ≥4 implies impaired awareness of hypoglycaemia. Clarke Score – A method used to assess impairment of awareness of hypoglycaemia. This comprises a set of 8 questions relating to hypoglycaemia where patient can score “1” or “0” for each question depending on response. A score of ≥4 implies impaired awareness of hypoglycaemia. Disabling hypoglycaemia – defined by TA 151 as the repeated and unpredictable occurrence of hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life. Severe hypoglycaemia – an episode of low blood glucose levels that requires assistance from another person to treat (i.e. a person unable to swallow, convulsing or unconscious). GPwSI in Diabetes – GP with Special interest in Diabetes DKA – Diabetic Ketoacidosis. EQ-5D – Validated Quality of Life measure developed by EuroQol and referenced by NICE. DQoL – Diabetes Quality of Life measure. A validated tool designed by the Diabetes Control and Complications Research Group. Intensive monitoring – For the purposes of the policy, patients who perform 8 or more additional blood glucose monitoring tests above the minimum frequency of daily testing outlined by NICE clinical guidance (i.e. 12 or more tests daily).

12	Appendix 2 – Applying NICE and RMOC guidance to the policy		
		Policy Section	**Guidance**
		1.2.1	**NG17 1.6.24** - “Real-time continuous glucose monitoring should be provided by a centre with expertise in its use, as part of strategies to optimise a person's HbA1c levels and reduce the frequency of hypoglycaemic episodes”.
		1.2.2	**NICE Quality statement [QS125], quality statement 4 “**Children and young people with type 1 diabetes who have frequent severe hypoglycaemia are offered ongoing real-time continuous glucose monitoring with alarms.” **NG17 1.6.22** “Consider real-time continuous glucose monitoring for adults with type 1 diabetes who are willing to commit to using it at least 70% of the time and to calibrate it as needed, and who have any of the following despite optimised use of insulin therapy and conventional blood glucose monitoring: • More than 1 episode a year of severe hypoglycaemia with no obviously preventable precipitating cause. • Complete loss of awareness of hypoglycaemia. • Frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities. • Extreme fear of hypoglycaemia. • Hyperglycaemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day (see recommendations 1.6.11 and 1.6.12). Continue real-time continuous glucose monitoring only if HbA1c can be sustained at or below 53 mmol/mol (7%) and/or there has been a fall in HbA1c of 27 mmol/mol (2.5%) or more.” **NG18 1.2.62** – “Offer ongoing real-time continuous glucose monitoring with alarms to children and young people with type 1 diabetes who have: • frequent severe hypoglycaemia or • impaired awareness of hypoglycaemia associated with adverse consequences (for example, seizures or anxiety) or • inability to recognise, or communicate about, symptoms of hypoglycaemia (for example, because of cognitive or neurological disabilities).” **NG18 1.2.63** – “Consider ongoing real-time continuous glucose monitoring for: • neonates, infants and pre-school children • children and young people who undertake high levels of physical activity (for example, sport at a regional, national or international level)

			• children and young people who have comorbidities (for example anorexia nervosa) or who are receiving treatments (for example corticosteroids) that can make blood glucose control difficult.”	
		1.3.1	**RMOC guidance** – “Until further trial data is available, it is recommended that audit data on the use of Freestyle Libre® is collected through its use in limited and controlled settings where patients are attending for Type 1 diabetes care.” “It is recommended that Freestyle Libre® should only be used for people with Type 1 diabetes, aged four and above, attending specialist Type 1 care using multiple daily injections or insulin pump therapy, who have been assessed by the specialist clinician……”	
		1.3.2	**RMOC guidance** – “It is recommended that Freestyle Libre® should only be used for people with Type 1 diabetes, aged four and above, attending specialist Type 1 care using multiple daily injections or insulin pump therapy, who have been assessed by the specialist clinician and deemed to meet one or more of the following: 1. Patients who undertake intensive monitoring >8 times daily 2. Those who meet the current NICE criteria for insulin pump therapy (HbA1c >8.5% (69.4mmol/mol) or disabling hypoglycemia as described in NICE TA151) where a successful trial of FreeStyle Libre® may avoid the need for pump therapy. 3. Those who have recently developed impaired awareness of hypoglycaemia. It is noted that for persistent hypoglycaemia unawareness, NICE recommend continuous glucose monitoring with alarms and Freestyle Libre does currently not have that function. 4. Frequent admissions (>2 per year) with DKA or hypoglycaemia. 5. Those who require third parties to carry out monitoring and where conventional blood testing is not possible. In addition, all patients (or carers) must be willing to undertake training in the use of Freestyle Libre® and commit to ongoing regular follow-up and monitoring (including remote follow-up where this is offered).”	
		1.3.3	**RMOC guidance** – “We suggest information is collected on the following: 1. Reductions in severe/non-severe hypoglycaemia	

			2. Reversal of impaired awareness of hypoglycaemia 3. Episodes of diabetic ketoacidosis 4. Admissions to hospital 5. Changes in HbA1c 6. Testing strip usage 7. Quality of Life changes using validated rating scales. 8. Commitment to regular scans and their use in self-management. We recommend that if no improvement is demonstrated in one or more of these areas over a 6 month trial then the use of Freestyle Libre® should be discontinued and an alternative method of monitoring used." **NG18 1.2.58 and 1.2.59** – "Advise children and young people with type 1 diabetes and their family members or carers (as appropriate) to routinely perform at least 5 capillary blood glucose tests per day." "Advise children and young people with type 1 diabetes and their family members or carers (as appropriate) that more frequent testing is often needed (for example with physical activity and during intercurrent illness), and ensure they have enough test strips for this." **NG17 1.6.11** - Support adults with type 1 diabetes to test at least 4 times a day, and up to 10 times a day if any of the following apply: • the desired target for blood glucose control, measured by HbA1c level (see recommendation 1.6.6), is not achieved • the frequency of hypoglycaemic episodes increases • there is a legal requirement to do so (such as before driving, in line with the Driver and Vehicle Licensing Agency [DVLA] At a glance guide to the current medical standards of fitness to drive) • during periods of illness • before, during and after sport • when planning pregnancy, during pregnancy and while breastfeeding (see the NICE guideline on diabetes in pregnancy) • if there is a need to know blood glucose levels more than 4 times a day for other reasons (for example, impaired awareness of hypoglycaemia, high-risk activities)	
		1.5	**NG28 (Full guideline)** - "The GDG discussed the conflicting evidence presented for continuous glucose monitoring compared with standard SMBG from 2 small, low-quality trials in people on insulin, where 1 trial	

			showed no difference in HbA1c levels at 3 months while the second trial showed a clinically important reduction in HbA1c levels at 12 months. The GDG agreed that there was still uncertainty regarding the effectiveness of continuous glucose monitoring. The GDG noted the overall lack of evidence on diabetes-related complications." **RMOC guidance** – "Until further trial data is available, it is recommended that audit data on the use of Freestyle Libre® is collected through its use in limited and controlled settings where patients are attending for Type 1 diabetes care." "It is recommended that Freestyle Libre® should only be used for people with Type 1 diabetes, aged four and above, attending specialist Type 1 care……"	

13	Appendix 3 – Patient groups and their eligibility for treatment

	Insulin pump	CGM	Flash GM
Neonates, infants and preschoolers	✓	x	x
Well controlled older	✓	x	x
Well controlled adults	x	x	x
Children with disabling hypos (as defined by TA155 excluding severe hypos)	✓	✓ (additional policy wording - when accompanied by loss of hypo awareness)	✓ (if pump not suitable)
Adults with disabling hypos (as defined by TA155 excluding severe hypos)	✓	✓ (additional policy wording - when accompanied by loss of hypo awareness)	✓ (if pump not suitable)
Children with frequent severe hypos	✓	✓	x
Adults with frequent severe hypos	✓	✓	x
Children with HbA1c ≥ 8.5%	✓	x	✓ (if pump not suitable)
Adults with HbA1c ≥ 8.5%	✓	x	✓ (if pump not suitable)
Children with HbA1c ≥ 9%	✓	✓	✓ (if pump not suitable)
Adults with HbA1c ≥ 9%	✓	✓	✓ (if pump not suitable)
Children with hypo unawareness	✓	✓	x (RMOC recommends in "recently developed hypo unawareness")
Adults with hypo unawareness	x	✓	x (RMOC recommends in "recently developed hypo unawareness")
Children with fear of hypo	✓	✓ (additional policy wording - if preferred to Flash GM)	✓ (additional policy wording - if intensively monitoring as a result of fear)
Adults with fear of hypo	x	✓ (additional policy wording - if preferred to Flash GM)	✓ (additional policy wording - if intensively monitoring as a result of fear)
Child intensive monitoring	✓	x	✓
Adult intensive monitoring	x	x	✓
Child third party monitoring	✓	x	✓ (additional policy wording - includes children unable to test frequently)
Adult third party monitoring	x	x	x

Included in the draft policy	✓
Not included in the draft policy	x
Included in NICE TA155	
Included in NICE clinical guidelines	
Included in RMOC guidance	
Not included in the NICE or RMOC	

14 Appendix 4 – Recommendations included in NICE / RMOC but excluded from the policy

	Criteria included in TA151 but omitted from policy	Criteria included in NICE CG but omitted from policy	Criteria included in RMOC but omitted from policy
Insulin Pump	None	N/A	N/A
CGM	N/A	1. Frequent asymptomatic hypoglycaemia (where patients don't suffer hypo unawareness) in all patients 2. Neonates, infants and pre-school children 3. Children competing at higher level sports 4. Children with co-morbidities 5. Undefined continuous hyperglcaemia in children (available in policy to children with HbA1c ≥ 9%) 6. All patients with extreme fear of hypo (including those not intensively monitoring)	N/A
Flash GM	None	N/A	1. All patients who qualify for an insulin pump to "avoid the need for pump therapy" 2. Those who have recently developed impaired hypo awareness 3. Frequent admissions (>2 per year) with DKA or severe hypo

Date of adoption
Date for review

Agenda item no. 7

Joint Committee of Clinical Commissioning Groups

Title of Paper	Engagement and Consultation Framework		
Date of Meeting	4th October 2018	Agenda Item	7

Lead Author: NHS TU/Freshwater		
Purpose of the Report	For Discussion	
	For Information	
	For Approval	Yes
Executive Summary:	Following feedback from members of the JCCCGs and legal advice, this final draft of the framework is presented to the Committee for formal **adoption**. The Framework is a mixture of legal and other mandatory requirements and also aspirational aspects in relation to best practice. These latter aspects could change in the light of learning from local engagement activities as well as from other parts of England. The JCCCGs will be apprised of any proposed changes as and when they are being recommended for adoption.	
Recommendations	The Committee is asked to **adopt** the Framework.	
Equality Impact & Risk Assessment Completed	Not Applicable	
Patient and Public Engagement Completed	Not Applicable, although the document describes the duties of the JCCCGs in relation to engagement and consultation	
Financial Implications	Not Applicable	
Risk Identified	Yes	
If Yes : Risk	Non-compliance with legislation and the required standards in relation to engagement and consultation, especially for proposals involving large service change, can result in successful legal challenges to those proposals.	
Report Authorised by:	Gary Raphael	

Engagement and Consultation Framework

The principles of involvement, engagement and consultation in Lancashire and South Cumbria

Joint Committee of the Clinical Commissioning Groups

Please note this document is the final draft

READER'S NOTES:

1. **This document contains proposals for the coordination of engagement and public consultation involving substantial change within the Healthier Lancashire and South Cumbria Integrated Care System.**
2. **The content is subject to approval.**
3. **Full appendices will be added later subject to approval.**

Introduction

Purpose

The purpose of this document is to set out:

a) The proposed governance process for the coordination of, and support for, engagement and consultation concerning substantial change to services across Lancashire and South Cumbria.
b) The proposed principles and framework the Joint Committee of the Clinical Commissioning Groups (JCCCGs) should adopt on behalf of itself and to guide other partners, including the ICS.

Together the principles and framework are designed to ensure modern, inclusive and meaningful involvement, engagement and consultation with patients, public, staff and stakeholders.

For the purposes of clarity this document is principally intended to assist Clinical Commissioning Groups (CCGs), Integrated Care Partnerships (ICPs) and the Integrated Care System (ICS) in the context of engagement and public consultation around substantial service change. It is not primarily intended to guide local, everyday patient and public engagement which should always be ongoing.

This document does NOT seek to address day-to-day, routine engagement activities that are undertaken by all NHS organisations.

This document DOES seek to address the activities and processes necessary for effective engagement and public consultation in the context of substantial service change.

It should be noted that this document provides GUIDANCE ONLY and the exact activities and processes should be determined by the needs of local people and communities potentially impacted by each service change programme.

Background

The partners across Lancashire and South Cumbria are committed to improving the health and wellbeing of their citizens. A cornerstone of this work is ongoing engagement with patients, public, staff, politicians and stakeholders.

In addition, however, the partners have identified several areas where there is a compelling need for significant change. Early engagement is already taking place in some of these areas, and further programmes of engagement or public consultation, led by the relevant CCGs, may be required.

Within Lancashire and South Cumbria partnership working across organisations is being facilitated through a new ICS, with more local ICPs being established to join up local services better within those places.

The table below shows public sector organisations within their ICPs:

Organisations	Integrated Care Partnership
Greater Preston CCG Chorley and South Ribble CCG Preston City Council Chorley Council South Ribble Council Ribble Valley Council Lancashire Teaching Hospitals NHS Foundation Trust	Central Lancashire
Blackpool CCG Fylde and Wyre CCG Blackpool Teaching Hospitals NHS Foundation Trust Blackpool Council Fylde Council Wyre Council	Blackpool and Fylde Coast
West Lancashire CCG West Lancashire Council Southport and Ormskirk Hospitals NHS Trust	West Lancashire
University Hospitals of Morecambe Bay NHS Foundation Trust Cumbria Partnership Foundation Trust Morecambe Bay CCG Cumbria County Council North Lancashire Medical Services South Cumbria Primary Care Collaborative Blackpool Teaching Hospitals Barrow-in-Furness Council Lancaster City Council South Lakeland Council	Morecambe Bay
Blackburn with Darwen CCG Blackburn with Darwen Council East Lancashire CCG East Lancashire Hospitals NHS Trust Burnley Council Hyndburn Council Pendle Council Ribble Valley Council Rossendale Council	Pennine Lancashire
Lancashire County Council Lancashire Care NHS Foundation Trust NHS England NHS Improvement North West Ambulance Service Innovation Agency (Academic Health Science Network)	Overarching organisations

The partners across Lancashire and South Cumbria have identified the following key objectives:

- To set out a clear direction of travel for the unified health and care system in Lancashire and South Cumbria as the Five Year Forward View has across England
- To achieve fundamental and measurable improvements in health outcomes by improving the clinical and social effectiveness of services focused on patient outcomes, effective use of resources and value for money.
- To reduce health inequalities across Lancashire and South Cumbria.
- To achieve parity of esteem for mental health and physical health across Lancashire and South Cumbria.
- To ensure greater focus on ill-health prevention, early intervention and self-care where this improves outcomes.
- To ensure that strategy and plans are created across Lancashire and South Cumbria to deliver effective and efficient integrated care services, in line with national requirements and timescales.
- To ensure change is supported by a clear evidence base or an evaluation structure where evidence is not available.
- To overcome organisational or professional boundaries that get in the way of progress; and integrate performance assessment processes across commissioners and providers in health and care services, to enable them to be held responsible for delivery of the sustainability and transformation agenda.
- To make maximum use of new technology when this will improve the quality of care provided.

To achieve these objectives, the Partners must develop a robust, effective and consistent approach to engagement and consultation and the Joint Committee of CCGs has therefore commissioned this paper to provide such guidance.

It is important to note that in law it is the local Clinical Commissioning Groups that hold the legal responsibility for ensuring that the public are involved in engagement and consultation for substantial service change, as well as ensuring it is conducted in a proper and appropriate manner. The Clinical Commissioning Groups carry the risks associated with any failures in this respect.

The ICS, on behalf of the public sector partners across Lancashire and South Cumbria, will facilitate the development of new models of care based upon the needs of local people and communities and it will need to engage clinicians and other care professionals, staff and wider partners such as local government. It cannot develop care coordinated and centred on the needs of patients and users without understanding what communities want and without the input of partners in local government.

NHS England guidance underlines the importance of involving people, communities and stakeholders in developing plans. It is the right thing to do to ensure such plans are robust and meet the needs of people and communities. ICP and ICS partners should work with the knowledge, skills and experience of people in their communities, working in co-production to improve access and outcomes.

Involving people, communities and stakeholders meaningfully is essential to effective service improvement and system transformation, from collectively identifying problems and designing solutions to influencing delivery and review. Effective communication and involvement throughout the process will help to build ownership and support for proposals to transform health and care and will also help identify potential areas of concern.

It is important that the ICP in every area has an ongoing dialogue with patients, volunteers, carers, clinicians and other staff, citizens, the local voluntary and community sector, local government officers and local politicians, including those representing health and wellbeing boards and scrutiny committees and local MPs.

It is essential that ICPs engage staff from constituent organisations, working through the internal communication channels available. In particular, it is important to engage clinicians who are powerful advocates and play an important role in communicating the need for change.

Coordinating engagement and consultation across the ICS

Role of the ICS and the CCGs

Clinical Commissioning Groups are legally responsible for ensuring that public involvement and consultation takes place through the practical and effective delivery of a public involvement or consultation programme. Such programmes are often delivered by a group of NHS organisations acting in concert (e.g. Committees in Common, Joint Committees of CCGs, a Sustainability and Transformation Partnership or an ICS) supported by external agencies which are often brought it to supply expertise and additional capacity.

In Lancashire and South Cumbria the ICS has full knowledge of all local strategies, plans and milestones. Using this knowledge, the ICS, as an agent of the CCGs, will coordinate and apply strategic oversight to all engagement and consultation work concerning substantial service change within the ICS geography. However, legal responsibility for the delivery of such engagement and consultation will remain with the CCGs.

The benefits of the ICS co-ordinating consultation and engagement activities when they relate to large-scale change across boundaries are:

- It will help ensure consistent messaging and feedback.
- It will enable one central point of co-ordination.
- It will ensure a consistency of approach.
- It enables best use of scarce staffing resources.

At present the ICS does not have the necessary staffing capacity or, perhaps, the full range of necessary skills, to deliver large-scale engagement and consultation as a fully in-house NHS function. It will therefore need to engage support from a range of external agencies such as engagement specialists, legal advisors, response analysts etc.

CCGs will… ensure that all major engagement and consultation work undertaken in Lancashire and South Cumbria are effectively coordinated through the offices of the ICS to ensure consistency of messaging.

The ICS will… seek to develop or procure additional engagement and consultation support as necessary.

The ICS will… ensure that whenever external resources are engaged there will be a strong emphasis on learning and skills transfer to help develop the skills of in-house NHS staff.

The ICS will… establish effective relationships with appropriate legal advisers and others.

The ICS will… collaborate with ICPs to share good practice, offer guidance, and coordinate activities where appropriate.

Governance process

Public consultation on matters that involve substantial service change carries with it significant legal complexity and considerable risks, not least risk to reputation. To mitigate these risks it is necessary to ensure a standard, best practice approach to public involvement and consultation and to ensure Lancashire and South Cumbria-wide coordination.

To facilitate the effective coordination of all major consultation and engagement activity across Lancashire and South Cumbria, a single view of all such activity will be required. Appropriate governance will be required to manage this.

On behalf of the CCGs the ICS will… establish a "Communications, Engagement and Consultation Strategy Board" with senior representation from each of the five Integrated ICPs and from NHS England/Improvement. This board will coordinate all engagement and consultation programmes involving substantial change that are undertaken within the ICS geography whether they be ICS- wide, ICP-based or local (see section on "Different types of change within the ICS"). The Communications, Engagement and Consultation Strategy Board will report to the Joint Committee of CCGs.

This board would not be overly bureaucratic, but it would help ensure ICS coordination alongside CCG legal leadership.

Different types of change

Engagement with patients, public, staff and stakeholders concerning the everyday delivery of health services is undertaken by health commissioners and providers as a matter of standard good practice. However, in addition, there are three distinct levels of "substantial change" that might require a significant engagement programme or even public consultation. These are:

- Lancashire and South Cumbria-wide service change or transformation
- ICP-wide service change or transformation
- Locality-led service change or transformation

Engagement or consultation concerning substantial change to services under any of these three headings should be considered by the Communications, Engagement and Consultation Strategy Board. It will consider and make recommendations as to the appropriate level at which engagement/consultation should be led/delivered. Key considerations include:

- Is there enough local capacity in the communication and engagement function to be able to take on this additional workload?
- Do the available in-house NHS communications and engagement staff have the necessary skills and experience to lead engagement activity?

Where the necessary engagement and consultation skills and experience are available from NHS staff they should be fully utilised. Certainly, knowledge of local stakeholders (such as Overview and Scrutiny Committees and other political interests) along with local relationships should be recognised as important criteria that are only likely to be available from local staff.

The ICS, on behalf of CCGs, will… use the "Communications, Engagement and Consultation Strategy Board" to assess the appropriate level for delivery of engagement and consultation (ICS, ICP or Locality)

Working with stakeholders across the system

There are many potential engagement partners in every health system. These include staff, patient representative groups, Healthwatch, third sector groups and voluntary groups. Their local knowledge and existing networks, as well as their independent status mean they can bring valuable extra resource and capacity to an engagement or consultation programme.

Specifically, local Healthwatch organisations are independent and support the principle of engagement and consultation without necessarily having a view on the consultation proposals. Their interest is in helping to ensure that people are informed, that they have opportunity to have their views and voices heard, and that decision-makers listen and take public views into account.

There are also a number of professional communicators and engagement specialists across the Lancashire and South Cumbria health system and it is important that we enable them to work closely together as a team. They have local knowledge and an understanding of the history of services, previous change programmes, knowledge of the local media, campaign groups and influential figures within their communities.

Another important set of stakeholders are those with political interests including local authority staff and officers, local elected members, health overview and scrutiny committees and local MPs. It is imperative that throughout any engagement or consultation programme these political stakeholders are kept full informed and involved.

To ensure the NHS makes maximum use of its in-house communication and engagement professionals:

The ICS, on behalf of CCGs, will… establish Communications and Engagement Steering Groups in each of its ICPs. These will be delivery-focused groups that report in to the Communications, Engagement and Consultation Strategy Board which will provide assurance to the ICS board and the Joint Committee of the CCGs.

The ICS will… establish appropriate Terms of Reference for both the Communications and Engagement Steering Groups and the Communications, Engagement and Consultation Strategy Board.

Engagement and consultation - Principles

Why engage and consult?

The NHS has a statutory duty to involve patients, the public, staff and other stakeholders in the development of health services. It is good practice to involve these stakeholders in the early stages of building any case for change. Involving communities and stakeholders in developing plans helps to ensure that service changes are robust and meet the needs of local people.

According to NHS England, “It is critical that patients and the public are involved throughout the development, planning and decision-making of proposals for service reconfiguration. Early involvement with the diverse communities, local Healthwatch organisations, and the local voluntary sector is essential… Early involvement will give early warning of issues likely to raise concerns in local communities and gives commissioners’ time to work on the best solutions to meet those needs.”

There are many benefits to the proactive provision of information along with effective engagement and consultation. These include:

- Developing a patient-focused service
- Encouraging greater public understanding and participation
- Increasing public awareness and education about NHS services
- Developing services that meet the needs of local people
- Improving relationships
- Generating new ideas
- Achieving cost efficiency and value for money
- Helping to plan, prioritise and deliver better services
- Improving health education and health outcomes
- Supporting the reduction of inequalities of outcomes and access.

In short, the NHS has a legal duty to involve and consult, this duty is underpinned by official guidance and experience suggests that effective engagement and consultation leads to better decision-making.

The ICS will… support CCGs to be proactive and take an inclusive approach to engagement and consultation to ensure that patients, public, staff and stakeholders are fully involved in the development of services from the earliest possible moment.

Definitions

Engagement and consultation can take different forms.

The term ‘engagement’ applies to two forms of communication:

- A continual process of building good relationships with partners and stakeholders through regular communications including face-to-face meetings. It should be a two-way dialogue of questions, answers and updates. Such activities should be planned, recorded and reviewed on a regular basis.

- An engagement programme can also be established for a set period during which a planned range of activities are undertaken. Typically, such programmes are focused on a specific issue or potential change and are often referred to as pre-consultation engagement.

‘Public consultation’ is a formal process lasting for a set period – usually 12 weeks – during which information is given and options for change are described in a public consultation document.

The JCCCGs will… be clear and honest with people that the results of public consultation are an important factor in health service decision-making.

The JCCCGs will… also be clear that the results of public consultation are not the only factor to be considered by CCGs in decision-making. Public consultation is not a vote on change nor is it a veto over any form of change.

The JCCCGs will… ensure that consultations demonstrate how different approaches have been considered and how public involvement has informed decision-making.

Legislation and best practice

There are a range of laws that govern public engagement and consultation in the NHS including:

- **The NHS Act 2006** (section 244) which requires commissioners to fulfil their duty to consult the relevant local authority in its health scrutiny capacity.
- **The Equality Act 2010** which requires all public authorities to have due regard to the public sector equality duty (section 149) when making decisions and.
- **Health and Social Care Act 2012 (amendment to The NHAS Act 2006)** which lays down duties in a wide variety of areas including duties as to improvement in quality of services (sections 13E and 14R), duties as to reducing inequalities (sections 13G and 14T), duties as to patient choice (sections 13I and 14V), duties with respect to public involvement and consultation (sections 13Q and 14Z2), duties with respect to variation in provision of health services, duties to promote the NHS constitution (section 14P) and duties as to promoting integration (section 14Z1).
- **The Health and Social Care (Quality and Safety) Act 2015** which lays down duties concerning the importance of sharing information (251B).

There are also several key guidance documents including:

- Cabinet Office – Consultation Principles (revised January 2016)
- NHS England – Planning, assuring and delivering service change for patients (revised March 2018)
- NHS England – Planning for Participation (May 2015)

In addition, NHS England says it is good practice when undertaking public consultation and pre-consultation engagement to have:

- An effective public communication and media handling plan.
- A detailed plan for reaching all groups who will be interested in the change, including those that are hard to reach, and those groups protected under the Equalities Act 2010.
- Staff involvement plans.
- Clear, compelling and straightforward information on the range of options being considered.

It follows from the above that the ICS will need a range of skills at its disposal including:

- Public and stakeholder engagement
- Staff engagement
- Media communication
- Reputational and crisis management
- Digital communication
- Publications (writing, design, print, distribution etc.)
- Consultation quality assurance etc.

The ICS will… support CCGs to adopt best practice when conducting engagement or consultation exercises and will support them to seek guidance, as necessary, from legal advisers and other appropriate consultants.

The principles of good engagement

The ICS will… support CCGs to establish a common, simple and accessible style in all published engagement and consultation materials that is:

- Clear and concise
- Easy to comprehend
- Jargon free and expressed in plain English
- Available in different languages and formats on request

The ICS will… support CCGs so that their public engagement and consultation documents are:

- Consistent with the style of communication described above.
- Not excessively long
- Supported with more detailed online information if necessary.

The ICS will… support CCGs to ensure, as appropriate, that engagement and consultation information is available publicly both online and as hard copy in a variety of public venues such as GP surgeries, hospitals, libraries etc.

The NHS England five tests

The public has a right to expect that any proposals for change that are raised by the ICS are affordable in capital and revenue terms and satisfy the five tests of service reconfiguration.

The five tests are:

- Strong public and patient engagement.
- Consistency with current and prospective needs for patient choice.
- Clear, clinical evidence base.
- Support for proposals from clinical commissioners.
- Service change which proposes plans to significantly reduce hospital bed numbers should meet NHS England's test for proposed bed closures and commissioners should be able to evidence that they can meet one of the following three conditions:
    - Demonstrate that sufficient alternative provision, such as increased GP or community services, is being put in place alongside or ahead of bed closures and the new workforce will be there to deliver it; and/or
    - Show that specific new treatments or therapies, such as new anti-coagulation drugs used to treat strokes, will reduce specific categories of admissions; or
    - Where a hospital has been using beds less efficiently than the national average, that it has a credible plan to improve performance without affecting patient care (for example in line with the Getting it Right First Time programme).

Furthermore, there is also a requirement that service changes align with local Sustainability and Transformation Partnership (STP) plans, as outlined in NHS England's updated guidance document, "Planning, assuring and delivering service change for patients".

The ICS will… support CCGs to apply the five NHS England tests to their engagement and consultation work and ensure consistency with the STP.

The Gunning principles

The Gunning principles are key standards, enshrined in law, that apply to all public consultations in the UK. They emerged from a legal case in 1985 (R v London Borough of Brent ex parte Gunning).

During this case Stephen Sedley QC proposed a set of principles that were adopted by the presiding judge and later confirmed by the Court of Appeal. These principles are now applicable to all public consultations that take place in the UK. They are:

- **Consultation must take place when proposals are still at a formative stage:** Meaningful consultation cannot take place on a decision that has already been made. Decision-makers can consult on a single proposal or 'preferred option' (of which those being consulted should be informed) so long as they are genuinely open to influence. There is no requirement, and it would be misleading, to consult on adopting options which are not genuinely under consideration, or are unrealistic or unviable – but it may be necessary to provide some information about arguable alternatives.
- **Sufficient reasons must be put forward for the proposal to allow for intelligent consideration and response:** Those being consulted should be provided with sufficient information to enable them to understand what the proposal is, the reasons for it and why it is being considered. They should be made aware of the basis on which a proposal for consultation has been considered and will be considered thereafter, including any criteria to be applied or factors to be considered. This may involve providing information about (or at least making reference to) arguable alternatives and the reasons why they are not also being

considered. The level of detail provided will depend on the circumstances.

- **Adequate time must be given for consideration and response:** People must have enough time to properly consider and respond to the consultation. There is no automatically required timeframe within which the consultation must take place.
- **The product of consultation must be conscientiously considered:** Decision-makers must properly consider what they have heard during the consultation when the ultimate decision is taken.

These principles were approved by the Supreme Court in R (Moseley) v Haringey LBC (2014) which also suggested that decision-makers should prepare a long list of options and indicate why some options are not realistic to consult on and make sure the public is consulted on all realistic options.

The ICS will… support CCGs to apply the Gunning principles to their engagement and consultation work.

Planning for consultation

When to consult

NHS proposals that involve substantial service developments or variations to a service amounting to a substantial development or variation of the health service should normally be the subject of public consultation. There is, however, no clear definition of "substantial" or major change and it is generally a matter for discussion with local health and care partners along with the relevant local authority Overview and Scrutiny Committees as to whether a potential change will require public consultation or engagement and if so, for how long.

Each proposal for service change therefore needs to be considered and assessed on a case-by-case basis. Sometimes it may be obvious that consultation is necessary (for example, if a major service is proposed for closure and it is not being re-located) but other proposals may be less clear-cut.

Some of the questions that will be considered when assessing the appropriate approach for a proposed service change are:

- What are the quality/safety benefits from the proposed change?
- What is the impact on patients/staff?
- What is the impact on other clinical and corporate divisions?
- Has there been any patient/user group engagement in developing the proposal?
- Is the proposal a temporary/time-limited or permanent service change?
- Does the proposal involve relocating a service to another site?
- How many patients would be affected?
- Where do the affected patients reside?
- What are the travel impacts for patients/carers/visitors?
- Does the proposal require an assessment of the equalities impact on affected patients?
- Are there financial or other non-clinical reasons for the proposed change?
- Which local authorities would have an interest in the proposals?
- What is the view of the local Health Overview and Scrutiny Committee?

Factors to be considered when determining the need for consultation or engagement include:

- Advice available from legal advisers.
- Advice available from system regulators and other consultants.
- Degree of local controversy (or likely controversy) around the issue.
- ICS risk appetite.

Service change proposals will also need to go through each stage of NHS England's assurance process, which helps to ensure proposals are robust and well thought through, risk is mitigated and there is consistency across the NHS commissioning system.

The ICS, on behalf of the CCGs, will… ensure that every service change proposal will have a simple, formal approval process (operating through the Communications, Engagement and Consultation Strategy Board) that determines the appropriate level of engagement or consultation.

Engagement and consultation timetabling

Engagement and consultation should be carefully planned and timetabled with active public involvement and the co-production of solutions. A best-practice consultation exercise would typically involve the following phases:

Phase 1 Scoping and planning stage

- Ongoing public involvement
- Establish a case for change
- Gather the relevant document library
- Scope the consultation
- NHS England strategic sense check (stage 1 assurance)
- Develop a narrative, key messages (Issues Paper)
- Map stakeholders
- Equality and impact analyses
- Plan pre-consultation engagement activities
- Identify and brief spokespeople

Phase 2 Pre-consultation engagement and consultation planning

- Pre-consultation engagement activity
- Options development and appraisal
- Update equality and impact analyses
- NHS England assurance checkpoint (stage 2)
- Develop consultation document and website
- Stakeholder Advisory Group
- Plan the consultation programme
- Tell people about it!
- Establish your logging and recording systems
- Publish your ideas and what you've heard to date

Phase 3 Consultation

- A mix of "traditional" and innovative activities
- Hard copy and electronic
- Take the consultation to people
- Be flexible and leave room for manoeuvre
- Achieve demographic balance

Phase 4 Post-consultation: analysis and decision-making

- Independent analysis
- Reflection and consideration
- Demonstration of impact
- Make informed decisions based on evidence
- NHS England post-consultation assurance (stage 3)
- Final consultation report and publish outcomes

The ICS will… support CCGs to adopt a common, phased approach to engagement and consultation as described above.

Impact assessments

Within each programme of work across the ICS, there must be consideration of the impact of change proposals on different population groups in terms of equality and human rights. Comprehensive health equality and inequality impact assessments should therefore be undertaken for every public consultation.

Impact assessments help the NHS meet its legal obligations to ensure that proposals do not unlawfully discriminate against individuals or groups, including those with protected characteristics. They play an important part in the design and content of consultation documents and activities and may also help identify any further assessment work that may be required (e.g. Travel Impact Analysis). Impact assessments are public documents and can and should be updated as options are developed during a consultation process.

Following decision-making, an action plan to address and mitigate inequalities will be developed to ensure statutory bodies meet their duties to reduce inequalities of outcomes and access.

The ICS will… support CCGs to produce impact assessments for every public consultation.

Consultation high-profile issues

Certain issues arise during engagement and consultation exercises with a high degree of regularity. These are not necessarily the most important or most significant aspects of any given engagement exercise, but they often become the public touchstone issues that attract publicity.

- The closure of key buildings: Even if a health service is continuing to be delivered from another nearby location, the closure of a well-known (and perhaps much-loved) health facility can attract significant opposition. Community hospitals – which have often been in a community for many years and often have strong Leagues of Friends – can general powerful sentiments.
- Travel times: There can be much misinformation over the time it takes to access services that are being relocated. This can revolve around the availability of public transport or the risk of traffic hold ups on busy roads. Members of the public sometimes express a preference for a poorer service that is near to hand rather than a better service that is further afield.
- Parking: The loss of parking facilities, or the fear of increased parking charges, are frequently cited as reasons for opposing change.
- Lack of clinical support: This is a concern that can prove fatal to any change programme. It is essential to establish, motivate and empower clinical support for change.
- Lack of information: It is frequently suggested that few members of the public know that an engagement or consultation exercise is taking place. It is essential to be able to demonstrate wide-ranging “reach” through metrics and statistics relating to media coverage, website visits, social media reach etc.
- Difficult questions: Health campaigners and politicians opposing change often try to overwhelm a health system with many detailed – and perhaps even unanswerable – questions. It is important to have a robust system that receives, logs and answers public questions.
- Key services: Certain services attract a disproportionate amount of publicity – often negative publicity. Maternity services, children’s services, A&E services and opening hours are examples of such issues.

The ICS will… ensure that all engagement and consultation exercises consider and respond to common high-profile issues.

Managing multiple consultations

There is a strong argument for holding related consultations concurrently wherever possible and appropriate. This helps ensure consistency of messaging and narrative, makes it easier to co-ordinate activities and improves the chances of raising public awareness.

It also saves time, public money and importantly, reduces the likelihood of consultation fatigue which would lessen the number of good quality responses in the form of feedback and attendance at events and activities.

The main drawback of holding all consultations at the same time, or under the same umbrella, is that a larger programme of preparatory work is required, and this necessitates more resource.

There is a chance that the public could be confused by multiple consultations taking place at the same time, though anecdotal evidence suggests that this also happens when consultation follows consultation.

If consultations are run concurrently, the NHS will need to guard against material interdependency of decision-making (e.g. one consultation making decisions which purposefully or inadvertently determine the outcome of another).

The ICS, on behalf of the CCGs, will… utilise the "Engagement and Consultation Strategy Board" to consider the merits of running consultation activity concurrently on a case-by-case basis.

Post-consultation

Challenges to consultation

The NHS Constitution says, “the NHS belongs to the people” and the Five Year Forward View says that at its best the NHS is, “of the people, by the people and for the people… [and] we need to engage with communities and citizens in new ways, involving them directly in decisions about the future of health and care services.”

To put it simply we have a strong public duty to engage and consult and to do so with honest intent. There is, however, a further practical reason for engaging and consulting properly.

Controversial consultations are often referred to the Secretary of State for Health by local authority Health Overview and Scrutiny Committees. The Secretary of State generally refers such cases on to the government’s Independent Reconfiguration Panel (IRP) for further consideration. This can lead to a delay in the implementation of transformational change or even to an IRP order that a consultation programme be completely rerun.

Perhaps the biggest risk is that of judicial review. Local campaign groups sometimes seek to thwart change by seeking judicial review of the public decision. The legal costs of defending a judicial review can run into many hundreds of thousands of pounds – which may not be recoverable even in the event of a legal victory – and since such reviews can take years to get to court, the cost of not implementing transformational change can itself run into many millions of pounds and can delay the implementation of patient improvements.

Therefore, it is advisable to ensure that engagement and consultation are conducted properly and subject to independent quality assurance, as well as NHS England’s thorough assurance process.

A public consultation is not necessary for every ‘minor’ change in the way a hospital functions or health services are arranged or provided. However, any proposal that will lead to a ‘substantial’ or major change in the way that local health services will be provided could become the subject of consultation.

It is also the case that, if an NHS commissioner or provider trust will be proposing ‘substantial’ changes to how health services are provided, it is the commissioner’s obligation to carry out a consultation and make decisions on any significant service change after the consultation period, therefore the consultation must be commissioner-led.

If the relevant local authority ultimately disagrees with the decision of the NHS body, or the process undertaken to reach the decision, it is entitled to refer the matter on to the Secretary of State for Health.

The ICS, on behalf of the CCGs, will… ensure all engagement and consultation are conducted properly and subject to quality assurance to mitigate the risk of challenge.

Decision-making

This is the final stage of a public consultation process. Views and opinions gathered during a consultation must be properly analysed and fully considered. Any decisions taken must take these views into account. A final report must then be widely publicised explaining the consultation process and the outcomes. This also marks the last stage of NHS England's assurance process – post-consultation assurance.

The ICS will… support the CCGs to follow best practice in decision-making post consultation by considering all views and opinions gathered, documenting how these have been taken in to account along with any associated decisions.

Appendices

Appendices to follow

- Hard to reach / seldom heard groups master list)
- Hard to reach / seldom heard groups (master list)
- Stakeholders (master list)
- Protected Characteristics groups (master list)
- Stages of engagement and consultation
- Engagement and consultation activities
- Cumbria case study & North Staffordshire case study
- Stakeholder Reference Group Terms of Reference
- 24/7 “always on” engagement

Joint Committee of Clinical Commissioning Group's

Title of Paper	Overview: Our Health Our Care (OHOC)		
Date of Meeting	4 October 2018	Agenda Item	8

Lead Author: Denis Gizzi			
Purpose of the Report: To provide an executive overview of the Central Lancashire Integrated Care Partnership and Acute Sustainability programme.			
	For Information		
Executive Summary			
Recommendations:			
Equality Impact & Risk Assessment Completed			Not Applicable
Patient and Public Engagement Completed			Not Applicable
Financial Implications			Not Applicable
Risk Identified			
If Yes : Risk			
Report Authorised by:			

Our Health Our Care

Lancashire Joint Committee of CCGs
Central Lancashire Integrated Care Partnership and Acute Sustainability Update
4 October 2018

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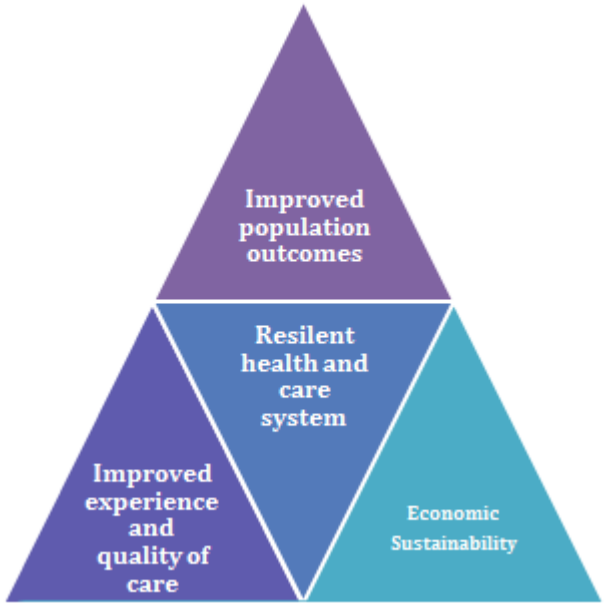
Overview of Central Lancashire ICP



Our Vision - Together, we will create a resilient health and care system, which will drive significant improvements in the wellbeing of our local communities, and will contribute to a sustainable central Lancashire economy

Update (September 2018):

- Central Lancashire Integrated Care Partnership Board established in Shadow form from April 2018
- Board Membership includes – Acute Provider / Community and Mental Health Provider / GPs / Commissioners (CCG) / County Council / District Councils / VCFS
- Recently completed initial recruitment to appoint an Independent Chair and an ICP Programme Director
- Builds on the Our Health Our Care Change programme, which has been in place since 2016
- Focus to date has been on form - emerging models, benefits, the value proposition and design principles through which the ICP will operate, as well as the Blueprint which defined how the system could look in the future
- We are now looking towards developing our big seven strategic platforms to deliver the change required in central lancashire

Our Big Seven Strategic Platforms

Our Big Seven … The main components of transformation

OHOC Strategic Platforms

The main components of transformation

Integrated Care Strategy

The way we go about transforming care systems to ensure truly integrated and optimal care

Integrated Care Partnership

The way leaders and care partners come together to oversee and deliver systematic value and sustainability, via a common purpose partnership

Out of Hospital & Wider Primary Care at Scale

The way we reshape the systems and processes of care delivery that distributes resources and care delivery into the out of hospital (community) sector

Acute Sustainability

The programme that governs all major acute service service change that requires public consultation

Economic & Financial Reform

The way we transform competitive processes into a single (Cent Lancs) integrated financial & economic control system

Clinical Care Reform

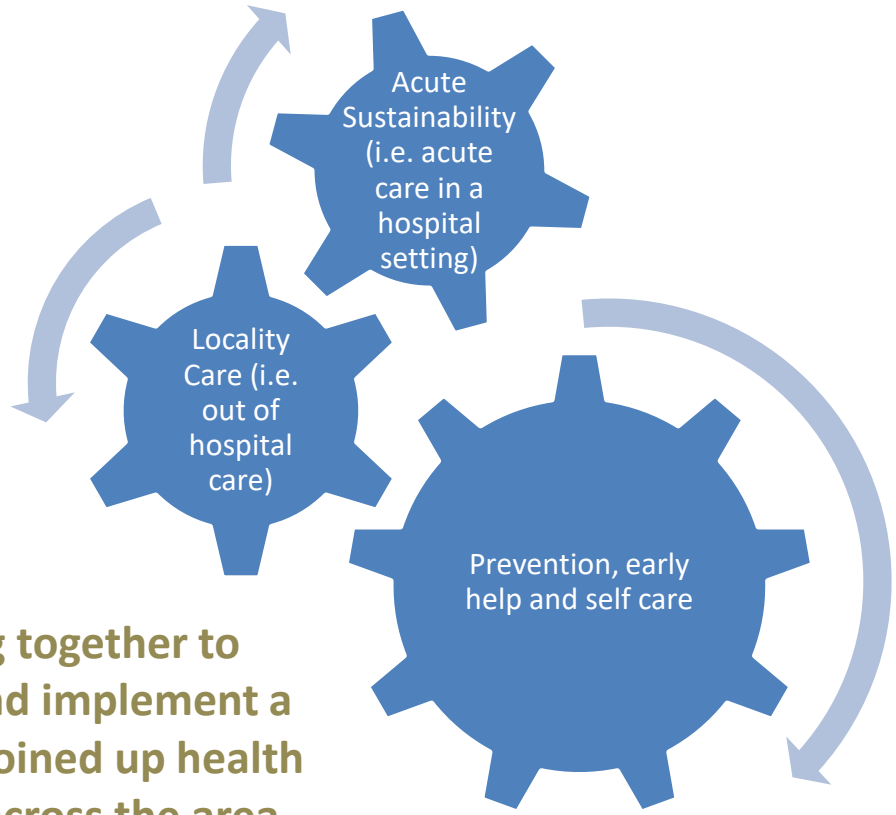
The way we re-engineer priority care programmes (e.g. Urgent Care) to become effective, efficient and person centered

Systems Management Reform

The way we re design the technical systems of commissioning into the central integrator function to drive efficiency, performance and value

Taking a more in-depth look at the Clinical change workstreams of Locality Care and Acute Sustainably

- Led by Greater Preston and Chorley and South Ribble Clinical Commissioning Groups – Denis Gizzi SRO
- Built upon three key workstreams



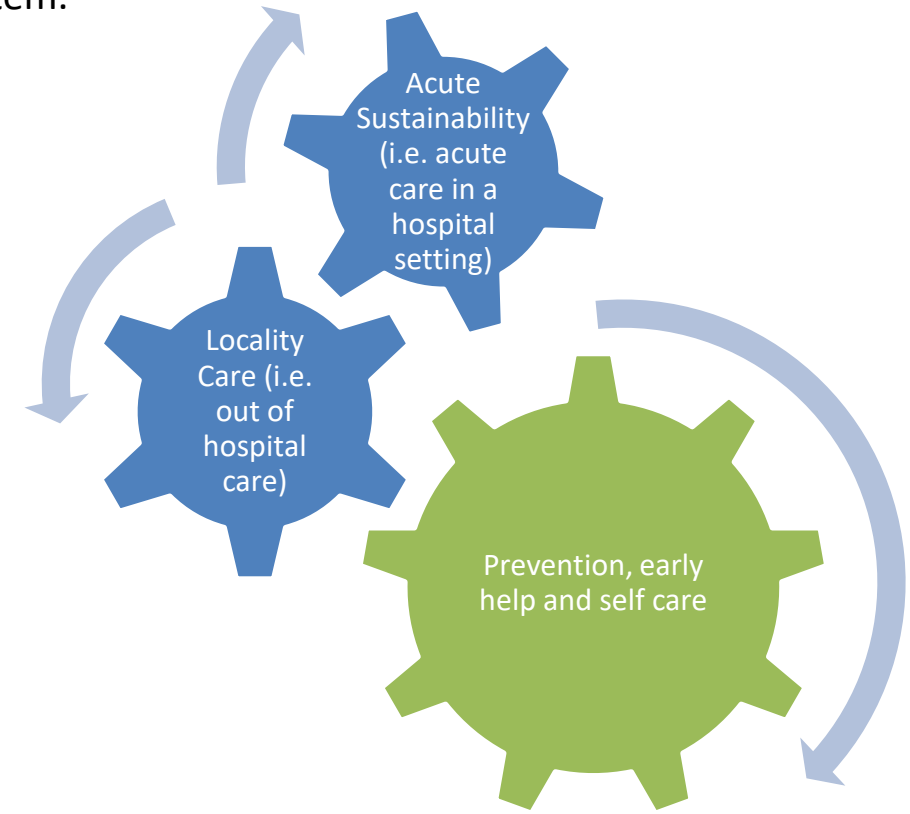
Working together to develop and implement a model for joined up health and care across the area

Specific aims:

- To encourage and enable people to take responsibility for **self-management** of their care with support from services to improve their health, wellbeing and quality of life
- To develop a more **person-centred approach** to health and social care, increasingly delivered within community, locality or home setting where appropriate.
- To develop **new models of health and social care** for our local health economy, rebalancing the provision of services to **reduce overdependence on acute hospital provision**
- To develop **new models of health and care that are clinically and financially sustainable** for the future and able to provide quality services that are safe, accessible, responsive and coordinated.
- To create models of care which will work within an **integrated health and care system**, tailored to the needs of our population and delivered in the right place at the right time.

Prevention and Wellbeing

- This strategy seeks a system-wide commitment to prevention through a ‘place based’ approach that utilises all of the resources to enable and maintain physical and mental wellness, build resilience and aid recovery. Delivery of this framework is built around developing prevention and wellness in four key areas; Culture, Community, Workforce, and System.



Key Focus

- Ensuring our population has good skills and access to **training, education and employment**
- Improving **community activity and engagement**
- Increasing **physical activity** and promoting wellness and **healthy lifestyles**
- Improving **homes** and **physical environment**

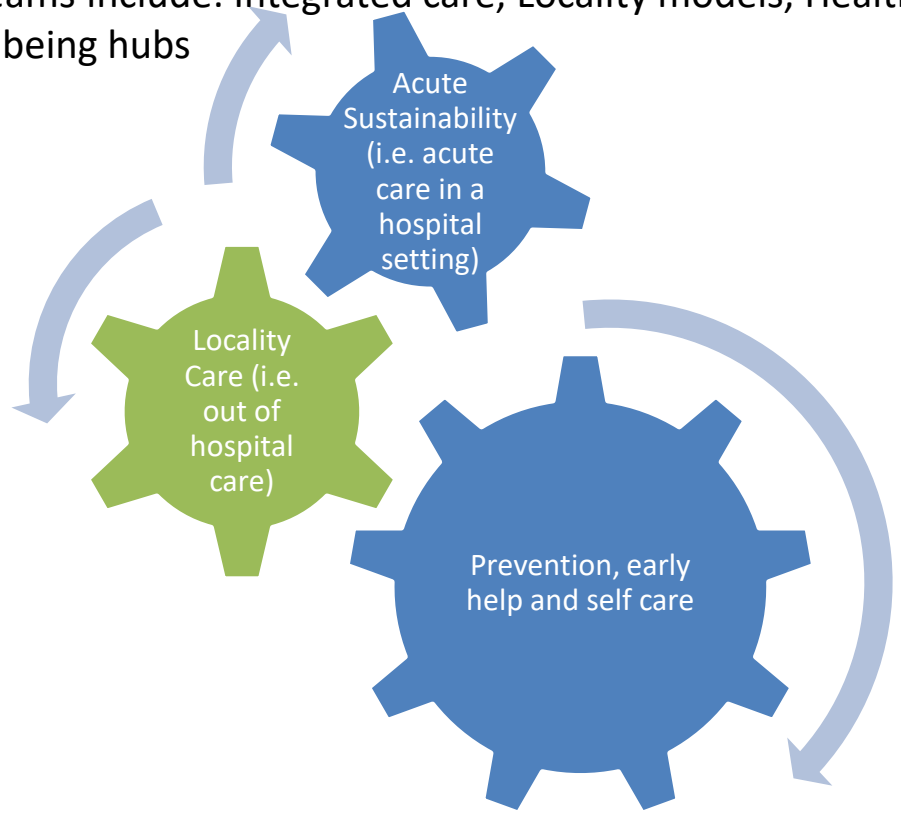
The adoption of this framework is to be achieved through system-wide changes to be actioned by organisations. In addition, integrated care teams will use this framework as a basis from which to develop their prevention actions and interventions with their community.

Benefits

- Communities will be healthy, empowered to help themselves and resilient to life’s challenges
- People will have access to education, employment opportunities and appropriate housing in a safe environment
- People will make valuable contributions and reap the rewards in terms of motivation, confidence and quality of life.

Out of Hospital

- Out of Hospital and Acute Sustainability programme are heavily interlinked, working closely together to achieve change
- In 2017 GPs from Greater Preston and Chorley and South Ribble co-produced an Out of Hospital strategy
- Aligned with several strategic plans – the SRO for the programme is Jayne Mellor
- Workstreams include: Integrated care, Locality models, Health and well being hubs



Integrated Care:

- To ensure patients have access to hospital services when needed by increased services delivered in the community, closer to home.

Locality Model:

- **Integrated care teams** will be formed to deliver primary care at scale shaped around local needs
- Localities will be supported to develop **a leadership model-at scale** that enables them to take responsibility for their population

Health and wellbeing hubs:

- **Centres developed in the community** to deliver integrated health and care to populations of 100,000 +
- Joins together primary care with community, secondary, social, mental health, diagnostics, prevention and possibly more

Benefits include:

- **Access:** Safe and accessible primary care services for all patients
- **New models of care:** Access to a greater range of services closer to home.
- **Integration:** Services from a range of providers delivered by a multidisciplinary team centred around the needs of the patient and community.
- **Workforce:** A valued and motivated primary care workforce with training and development opportunities
- Technology

Out of Hospital progress-to-date

Investment

- £1 per head of population was invested in 2017/18 to support practices coming together as informal groups to start to work on delivering 7 day access
- The remaining £2 is to be invested in 2018/19

Primary Care at Scale

- All practices in Greater Preston are working in networks
- All practices in Chorley and South Ribble have been identified in a network but the practicalities of this are still being worked through with a small number of practices

Extended Access

- Coverage in Greater Preston is now 100%
- GP Quality requirements include practices to open 08:00 – 18:30 Monday to Friday

Integrated Care Networks

- All practices within both CCGs are included within an Integrated Care Team. There are some discussions taking place within C&SR in regards to some minor alterations to a couple of the footprints
- Several pilots now underway including Diabetes pathway / Care Home Model

Locality Hubs

- Capital Bid Completed and approved by the Integrated Care System.

General

- 100% Greater Preston and 90% Chorley and South Ribble practices are working in collaboratives
- Seven day access is being delivered to approximately 97% of the population with plans in place for the remaining by October 2018
- Care home service commenced in 50% of the collaborative with plans to deliver 100% coverage

Acute Sustainability – Case for Change

Key Pressures

1. Significant growth in the needs of the population
   - Structural health inequalities that we need to tackle together as a system
   - People living longer and more patients presenting with frailty, long term conditions and co-morbidities increasing pressure on our hospitals
2. Workforce supply not sufficient to safely staff services duplicated across two sites

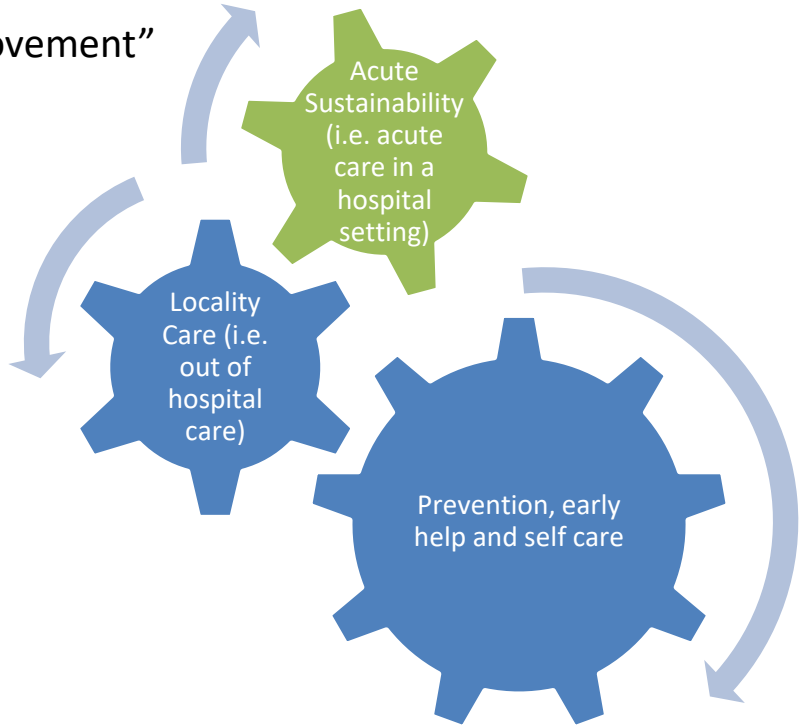
- *In Preston 37% of the population live in the most deprived areas in England*

- *Number of people over the age aged 65 set to increase by 33,000 by 2037*

- *Gaps in medical staffing within the acute medical workforce that difficult to fill – overreliance on locums*

Impact on care for patients

- High bed occupancy (93%) means
  - ➢ Delays from decision to admit to admission
  - ➢ Excessive A&E waits – 60% January 2018
  - ➢ Volume of demand and medical outliers generating planned surgery cancellations and decrease in planned surgery
  - ➢ Excessive RTT including cancer waiting times
- Variation in meeting staffing standards
- "Requires Improvement"



Work underway to develop a range of scenarios

- **Scenarios not yet agreed**
- Analysis will consider "Do nothing" (services retained as is) and a range of other scenarios
- Emerging concepts being tested with the public and clinicians are as below

	What	Why could this improve care for patients
Urgent, emergency and critical care	• Integrated partnership care with specialist support and advice to GPs and teams wrapped around the patient, joined up primary care pathways • a new clinically-led model of urgent and emergency care • Standardised Ambulatory Care Unit(s) • Frailty Assessment Unit/enhanced virtual Frailty Assessment across Central Lancashire • Critical care level and capacity re-designed to meet demand	• Care more joined up with primary care • Sustainable staffing model that makes best use of limited skilled staff and is able to meet national staffing and 7 day standards • Specialisation of "once in a lifetime" emergency surgery service • Improved use of ambulatory care, reducing patient waits • Improved access to frailty support • Adequate critical care capacity • Reduced bed pressures, reducing waits for a medical bed and A&E waits
Women's and children's services	• Women's and children's services retained as-is	• Continued access to an MLU at both sites • Continued access to Obstetrics and Paediatrics
Planned care	• Planned Care Treatment Centre (no emergency surgery) • Single access booking and streaming of patients	• Significant reduction in cancellations, RTT and waits for planned surgery – including cancer waits

Work underway to involve the public and other stakeholders

Activity snapshot

Two main periods of activity:

Period 1: Sept 2016 – March 2017 (18 public engagement events, outreach engagement with seldom heard groups (examples below:

Presentation to the Chorley Equality forum with (35 people)	Session with Galloway's society for the blind and (30 service users)	Presentation to the Preston and District Carers Support Group (15 people)
Question time event with Preston's College students (148 students, 12% from BME backgrounds)	Engagement at a community coffee morning at Ingleton Congregational Church, (approx. 45 people)	Stand at the Preston Health Mela (engaged approx. 40 people)

Period 2: March 2018 – Present (public engagement events, outreach engagement, two online surveys, targeted conversations with specific groups)

Events have been led by clinicians

Activities have taken place across Leyland, Chorley and Preston

Between September 2016 and September 2018 we have engaged face-to-face with approximately 1,950 people of which approximately 750 have been a public engagement events

Aa programme of targeted conversations and engagement with specific groups, included:

- Young LGBT people
- People who identify as transgender
- People with visual impairments
- People with learning disabilities
- Asian women
- Black African / Caribbean men

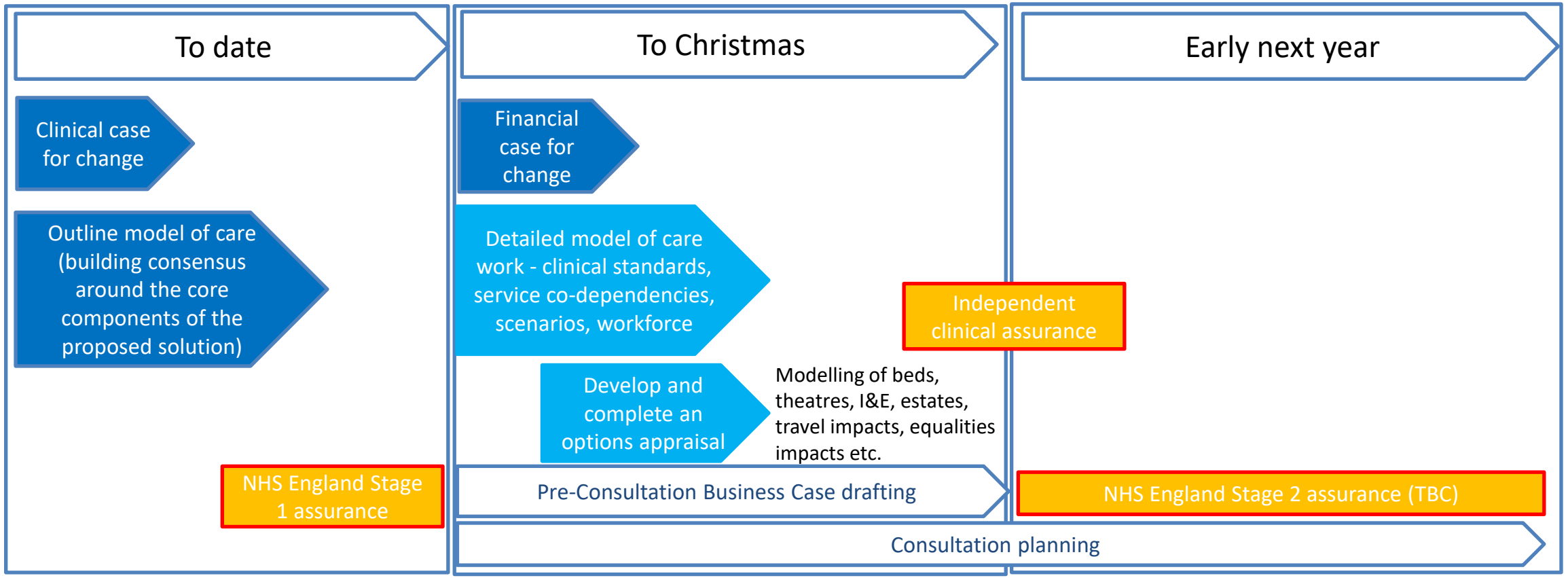
Representation of the population is being tracked in relation to characteristics and demographics.

A Patient Advisory Group has been involved in the programme throughout, which is a group that represents other patient and community groups, and covers Equality Act 2010 protected characteristics – they provide reference and advice in relation to process and information materials.

In addition, there have been extensive stakeholder conversations, including with the voluntary, community and faith sector, GPs, hospital staff, partner organisations, MPs and councillors.

Next steps

- Strategic sense check 1 complete

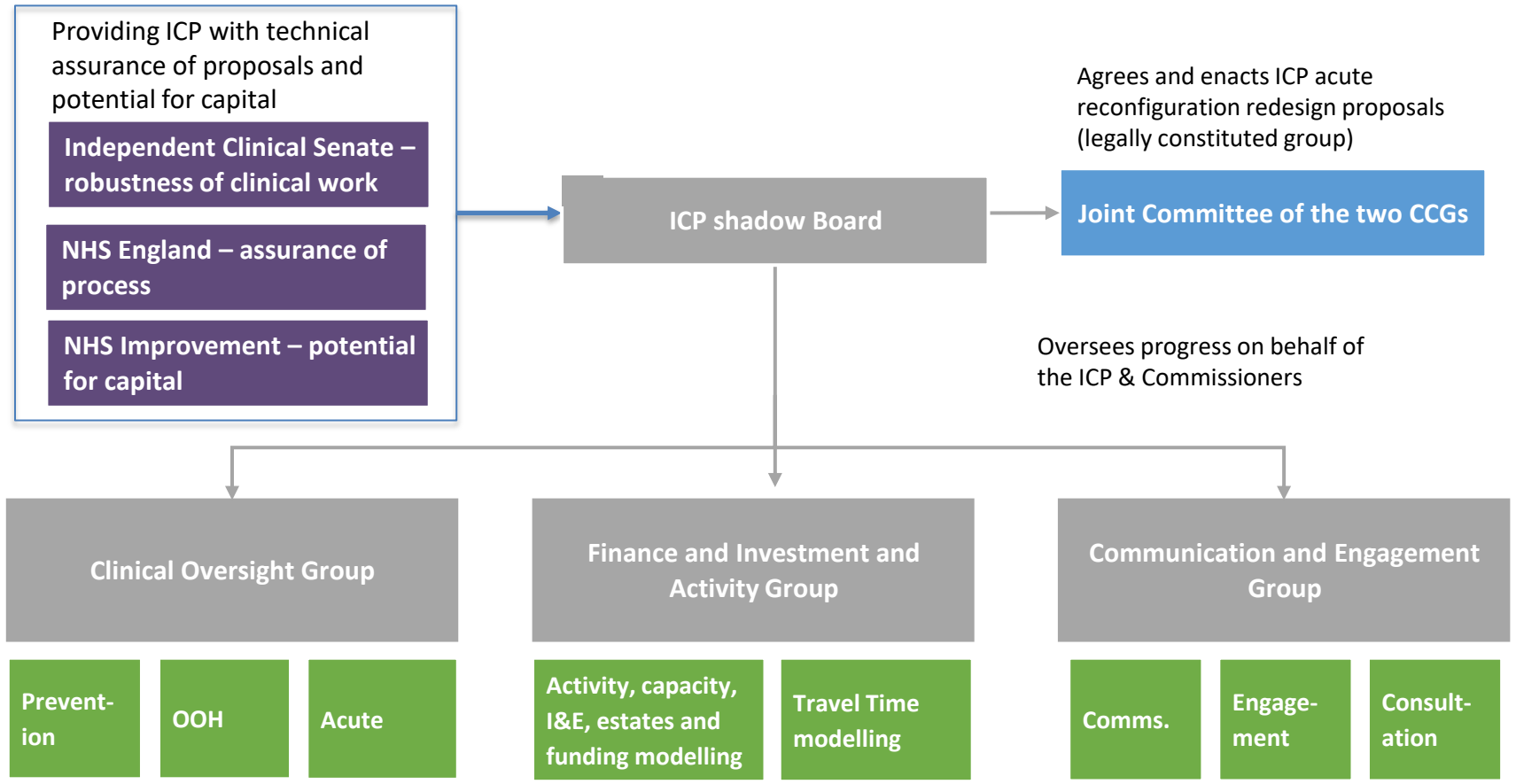


Next steps:

- Build clinical design - a coherent out of hospital and acute model
- Agree scenarios
- Agree an options appraisal approach, with public involvement and initiate the options appraisal work - what does each scenario mean for activity, beds, theatres, workforce, capital, I&E, estates, patient travel, protected groups etc.
- Agree senate and NHSE assurance timeline
- Agree consultation go-live date

OHOC Governance Structure

- CCG leadership
- Decision-making by specifically constituted OHOC Joint committee of two CCGs
- Denis Gizzi SRO



Stakeholder input into design, for example:

Central Lancashire Health & Wellbeing Partnership

Patients

Health Watch

Key

- Governance group (decision-making)
- Design package
- Formal role in assurance or capital
- Programme management (not decision-making)