A Gold Standard Time to Diagnosis in Axial Spondyloarthritis

Consultation Document
What are we proposing and why?

Axial spondyloarthritis (axial SpA) is a form of inflammatory arthritis that most commonly affects the spine. It is a painful and progressive long-term condition affecting approximately 220,000 people in the UK (1 in 200), for which there is currently no cure.

In the UK, it takes on average 8 ½ years for someone living with axial spondyloarthritis (axial SpA) to be diagnosed. During this time people can experience significant amounts of pain and anxiety and they often pay a heavy physical and psychological price for this delay. Symptoms typically begin in early adulthood (average age of 24) when people are trying to establish careers, start relationships and families, so a delay to diagnosis can be incredibly disruptive to someone during their formative years.

In recognition of these considerable burdens placed on many individuals, our Gold Standard aim is to work collaboratively with key stakeholders to transform the average time to diagnosis throughout the NHS from 8 ½ years to one year. Doing so will deliver dramatic health and wellbeing improvements for those affected, enabling more patients to access appropriate treatment earlier and improve their health and well-being, thereby helping the NHS to become a global leader in axial SpA service delivery.

We have identified four main sources that we contend are responsible for the current average 8 ½ year delay in axial SpA diagnosis, alongside four potential solutions that we believe would help to deliver a much-needed transformation in the area:

**Delay 1:** People do not know that axial SpA may be a cause of their chronic back pain

**Delay 2:** General practitioners (GPs) may not recognise features of axial SpA

**Delay 3:** People may be referred to non-rheumatologists who may not promptly recognise axial SpA

**Delay 4:** Rheumatology and radiology teams may not optimally request or interpret investigations

**Solution 1:** Help the person with inflammatory back pain to recognise that it might be axial SpA

**Solution 2:** Ensure swift identification of potential axial SpA in primary care

**Solution 3:** Ensure direct referral to rheumatology

**Solution 4:** Ensure that patients get a timely diagnosis from the rheumatologist
There has been growing momentum for change over the last two years on which we can build. In 2017 NICE produced the first national clinical guideline for the diagnosis and management of spondyloarthritis and in 2018 produced an accompanying Quality Standard to guide NHS commissioners and providers in several key improvement areas. In December 2018 NASS launched our Every Patient, Every Time campaign in the House of Commons. This included the establishment by NASS of the first ever All Party Parliamentary Group (APPG) on axial SpA. In March 2019 the APPG commissioned a national inquiry into the implementation of the NICE guidelines and its report found significant shortcomings across the country.

The consultation document represents the next stage in this journey. It sets out the four delays and solutions in more detail and proposes a Gold Standard time for each stage of the diagnosis pathway. It then lays out a proposal for developing a four-year national implementation plan to achieve full implementation of the Gold Standard.

What are we asking you to do?
As set out in the accompanying consultation document, we are keen to engage key stakeholders such as yourself on these proposals, seeking your input on their scope, aims and proposals, and how you feel your organisation is best-suited to support this process.

Specific consultation questions and information on the consultation process are set out in the accompanying document, asking for feedback on the detailed Gold Standard proposals set out below.
The current delay to diagnosis and its impact

Why do we need to improve delay to diagnosis? Two independent reviews\textsuperscript{5,6} found significant delays to axial SpA diagnosis worldwide with a mean of 6.7 years – substantially longer than the 2.6 years for a similar condition, psoriatic arthritis. The average delay across 9 UK studies was 8.7 years, longer than many other countries (Table 1).

Table 1. Mean diagnostic delay in axial SpA across different countries.

<table>
<thead>
<tr>
<th>Country</th>
<th>No. of studies</th>
<th>Mean delay, years</th>
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<tbody>
<tr>
<td>UK</td>
<td>9</td>
<td>8.7</td>
</tr>
<tr>
<td>Italy</td>
<td>3</td>
<td>7.7</td>
</tr>
<tr>
<td>Iran</td>
<td>4</td>
<td>6.4</td>
</tr>
<tr>
<td>Turkey</td>
<td>10</td>
<td>5.9</td>
</tr>
<tr>
<td>China</td>
<td>4</td>
<td>4.3</td>
</tr>
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</table>

Within the UK, delay ranged from 5.7 years among service personnel at Headley Court to 11 years in North Liverpool (Table 2). The latter was a study of patients at their first specialist spondyloarthritis review,\textsuperscript{7} showing that delay to referral can be significant in parts of the country.

Table 2. Mean diagnostic delay in axial SpA reported by studies from the UK

<table>
<thead>
<tr>
<th>Study</th>
<th>Location</th>
<th>Mean delay, years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jones 2014</td>
<td>Headley Court</td>
<td>5.7</td>
</tr>
<tr>
<td>Owusu-Agyei 2019</td>
<td>Luton &amp; Dunstable University Hospital</td>
<td>7.1</td>
</tr>
<tr>
<td>Sykes 2015</td>
<td>Bath &amp; Norwich</td>
<td>8.5</td>
</tr>
<tr>
<td>Hamilton 2011</td>
<td>NASS survey</td>
<td>8.6</td>
</tr>
<tr>
<td>Moran 2016</td>
<td>Lancaster</td>
<td>8.9</td>
</tr>
<tr>
<td>Zhao S 2018</td>
<td>BSR biologics register</td>
<td>9.6</td>
</tr>
<tr>
<td>Gunasekera 2014</td>
<td>Bath</td>
<td>10.5</td>
</tr>
<tr>
<td>Zhao S 2019</td>
<td>Liverpool</td>
<td>11.1</td>
</tr>
</tbody>
</table>

Two studies from the UK have shown that there has been no meaningful improvement in axial SpA diagnostic delay over time\textsuperscript{8,9}. In stark contrast, time to diagnosis has improved in many other countries; for example, Italy (from 7.4 years in the 1990s to 2.1 years in the 2000s\textsuperscript{10}) and Japan (7.5 years before 2000 to 3.6 years after\textsuperscript{11}).

Factors associated with delay differed from study to study. Delay was consistently longer among patients who: 1) did not have other (“extra-articular”, i.e., psoriasis, uveitis, inflammatory bowel) features, 2) had lower levels of education, and 3) developed symptoms at a younger age. Several studies also reported longer delay among female patients\textsuperscript{8,12} and among those who were HLA-B27 negative\textsuperscript{13,14,4}. 
Impact on patients

Patient with delayed diagnosis tend to experience a range of poorer outcomes.\textsuperscript{15} Longer delay is consistently linked with poorer functional impairment; one study found mean spinal mobility impairment (measured using the Bath AS Metrology Index) to be over twice as high in those with delay of longer than 6 years compared to shorter.\textsuperscript{15} Many studies also showed links between delay and greater damage on X-ray images; 77\% of those with delay of longer than 8 years had abnormal changes on X-ray images of the spine, compared to 45\% with shorter delay.\textsuperscript{15} Because of this, patients with longer delays to diagnosis report poorer quality of life and higher prevalence of depression. An Irish study compared patients with ≥7 years of delay to those with <7 years and found significantly higher portion of depression among the long delay group (16\% vs 9\%).\textsuperscript{16} Underdiagnosis of depression is well-recognized; the true prevalence of depression in those with an axial SpA diagnosis is likely to be 38 to 52\% overall.\textsuperscript{17} Once diagnosed, 69\% of patients in an Australian study reported emotional relief and 76\% a positive shift in perception of symptoms.\textsuperscript{18} In this study, 80\% felt that physicians could devote more time to try to establish a diagnosis and 70\% that their diagnosis could have been established earlier.

Costs to individuals and society

Diagnostic delay comes with significant costs to the individual and society. In the same systematic review referenced above,\textsuperscript{15} all studies unanimously reported that delay was associated with higher risk of work disability or unemployment. Diagnostic delay was consistently associated with job loss. For example, an Irish study showed that unemployment rose from 20\% among those diagnosed within 4 years, to >40\% among those with delay of >10 years.\textsuperscript{19} In a Chinese study comparing patients with delay of ≥8 and <8 years, 28\% of patients had to stop education/employment in the longer delay group compared to 13\% in the shorter delay group.\textsuperscript{20}

To date, there have been no health economic studies of diagnostic delay in the UK. The indirect effect of delay (through greater disease severity described above) has been shown potentially to double the cost to the NHS.\textsuperscript{21} An Egyptian study found that patients with longer delay had nearly 3-times higher number of visits to the doctor prior to diagnosis, amounting to a near-4-fold higher expenditure. This was replicated in an Australian study, where a quarter of patients with <5 years’ delay incurred high treatment costs (>3000 US Dollars), compared to two thirds among those with >10 years delay.\textsuperscript{18} These trends may well be present in the UK also.
Four delays

Delay 1: The person with back pain does not realise that it might be axial SpA.

There are many other causes of back pain; these individuals might think that they have sprained their back through some exertion at work or sports injury. This was commonly reported in interviews with axial SpA patients. Symptoms of axial SpA often come and go, where pain might be awful for two months but then subside, which is when people might dismiss symptoms or cancel their appointment. Only 30% of axial SpA patients are presenting to a healthcare professional within three months of their symptoms starting. 40% wait more than one year before they see a healthcare professional, which may be an osteopath or chiropractor in 40% of cases, many of whom may not have specialist axial SpA knowledge.

Delay 2: The primary care practitioner may not recognise axial SpA.

Some misconceptions about the condition remain among GPs. For example, the Oxford Handbook of General Practice still refers to late stages of axial SpA (i.e., Ankylosing Spondylitis) with a focus on male predominance and late disease features such as fusion of the spine or sacroiliac joints. However, we now know that early disease will not show bony fusion on radiographs, and that ≥50% of patients with such “non-radiographic” axial SpA are women. Many textbooks also cite ≥95% of patients being HLA-B27 positive, leading clinicians to believe that a negative HLA-B27 can exclude the diagnosis. We now know that up to 20% of those with advanced axial SpA (i.e., AS) can be negative, with an even higher proportion of non-radiographic axial SpA cases testing negative. Symptoms in these non-textbook cases are often diagnosed as spinal disc problems. When interviewed, patients often describe experiencing negativity and reluctance from GPs to investigate or refer. Furthermore, patients often find it difficult to convey their symptoms to the GP, since there are often few or no physical signs.
Delay 3: When the person with symptoms suggestive of axial SpA is not directly referred to rheumatology services.

One example – which unfortunately is commonly repeated - is an individual in her 20s who had been to three orthopaedic surgeons and undergone four sets of MRI scans (of the wrong type), and after six years was referred to a rheumatologist who found inflammation using the correct MRI sequence. Many cases of unexplained chronic back pain can be referred to pain clinics where people are unnecessarily started on conventional pain medications, when prompt anti-inflammatory medications can relieve their symptoms. In an increasingly subspecialised and overwhelmed health system, healthcare providers may only have resources to focus on one aspect of a complex of symptoms. For example, axial SpA can be a cause of early hip osteoarthritis, yet there are cases of young people undergoing total hip replacement without recognition of their undiagnosed axial SpA.27 There are also cases of uveitis in ophthalmology, inflammatory bowel disease in gastroenterology/surgery or psoriasis in dermatology services who, when asked about their back, report axial SpA symptoms that had been missed.28 Thus pain, psychology, surgical and other related medical services may benefit from education to improve the often-convoluted referral pathway to rheumatology.

Delay 4: When the patient is referred to a rheumatologist who may not have the most up to date understanding of the condition or its investigation.

This may start from the wrong type of MRI sequences being ordered (specific sequences are needed to pick up the condition). Radiologists may not then be familiar with patterns of subtle inflammation suggesting axial SpA. Dr Helena Marzo-Ortega - a consultant rheumatologist from Leeds - led two seminal papers29,30 to guide radiologists which recommend the optimal sequences and how to interpret them. These papers are published but wider dissemination among relevant healthcare professionals is needed.
Four Solutions

Solution 1: Help the person with inflammatory back pain to recognise that it might be axial SpA.

We think this should be done through a series of national awareness campaigns involving public health bodies, NASS, rheumatology departments, occupational health organisations and a whole host of others. In 2020 we have the advantage of social media, websites and other tools to help us. For example, the ‘Don’t Turn Your Back On It’ campaign\(^3\) in 2014 included a website that helped people with back pain check for inflammatory features and print the results to share with a healthcare professional and ask: ‘could I have axial SpA?’ This was an effective way to increase public awareness.

Our proposed Gold Standard Time for Diagnosis aims for no more than 4 months from symptom onset to booking an appointment in primary care.

Solution 2: Swift identification and referral of people with suspected axial SpA in primary care.

This might be difficult because primary care practitioners have a significant workload and see a vast range of different conditions, but there are some tools in place to help. For example, there is an excellent infographic from the British Medical Journal that was sent to all GPs across the UK to help recognition of axial SpA. Appropriate bodies should facilitate education for all primary care professionals so that they can recognise axial SpA: Clinical Commissioning Groups and Primary Care Networks in England; GP Clusters working collaboratively with Locality Networks in Wales; NHS Boards in Scotland; and Local Commissioning Groups attached to the Health and Social Care Boards in Northern Ireland. These organisations should work in partnership with their national educational body where appropriate (Health Education England, Health Education and Improvement Wales, NHS Education Scotland – no equivalent in Northern Ireland).

In the South West of England, Dr. Sengupta has successfully implemented a tool on the GP electronic patient record system. Under this pilot, when a GP types “back pain” the system checks whether the person is under the age of 45, and whether they have previously had back pain. If the answer to these is yes, it prompts consideration of axial SpA. It can also be programmed to alert the GP of possible axial SpA if the patient has had uveitis, psoriasis or inflammatory bowel disease in the past. Dr. Sengupta is continuing to optimise this alert system. NASS, working with Professor Gaffney, Dr Sengupta and Dr. Jane Martindale, brought together osteopaths and chiropractors to develop a referral template endorsed by the Royal College of GPs. Now osteopaths and chiropractors can forward a template to the GP to facilitate prompt referral to rheumatology.
In addition, the creation of First Contact Practitioner roles in primary care offers a significant opportunity to ensure early identification and onward role of suspected axial SpA patients.

The proposed Gold Standard Time here is 2 weeks for the GP appointment, in line with a recommendation from the Assessment of SpondyloArthritis International Society (ASAS) for immediate referral to rheumatology (within 3 days) once axial SpA is suspected.32

Solution 3: Ensure direct referral to rheumatology.

The main way to implement direct referral to rheumatology is to ensure that inflammatory back pain pathways are in place for CCGs in England, Locality Networks in Wales, NHS Boards in Scotland and Local Commissioning Groups in Northern Ireland. We need to continue working with ophthalmology, gastroenterology, dermatology and surgical colleagues to ensure that they understand the pathway. A large amount of work has been done through NASS to create information for these services, but more is needed. Rheumatology services should be providing training and support to other secondary care services.

The Gold Standard Time here is that all patients should have their first appointment in rheumatology within 18 weeks. This is consistent with the ASAS quality standards, which recommend rheumatology assessment within 3 weeks after referral.32

Solution 4: Ensure that patients get a timely diagnosis from the rheumatologist.

Rheumatology and radiology training is critically important. There are examples of rheumatologists training radiologists and rheumatologists in the UK to recognise axial SpA features on radiology imaging, but wider engagement is needed along with the aforementioned imaging protocols developed by Dr Marzo-Ortega. For example, one of these has provided a free service33 to radiologists in District General Hospitals to obtain advice and guidance for images that they are not sure how to interpret. These technologies can be used to help early diagnosis.

The Gold Standard Time here is that all patients should be diagnosed within 3 months of their first rheumatology appointment, which involves performing and interpreting all investigations in this period. This is consistent with the ASAS quality standards which recommends all investigations are completed within 2 months after the first rheumatology appointment.32
Axial SpA patients in the UK experience some of the longest delays to diagnosis in the world. Ensuring that each of the above 4 solutions is implemented in full would result in patients being diagnosed within one year of symptom onset, transforming axial SpA care and outcomes in the process. The below section sets out further details and proposed tactics for how each of these proposed solutions can be achieved.

An integrated national implementation plan
To achieve the Gold Standard will require committed, sustained and integrated action from those working in primary and secondary care services, commissioners, third sector organisations and arms-length bodies. We set out below further detail about our proposed solutions which will form the basis of an implementation plan for 2021 – 2024 with four strategic priorities, as follows:

To help people with symptoms to recognise earlier that it might be axial SpA and then consult primary care
Public awareness of axial SpA will need to be improved if people are to recognise their symptoms earlier and consult a healthcare professional. Systematic review of mass media interventions in a range of health conditions has reported a positive effect on information seeking and health services utilisation.34 However, in order to ensure an enduring impact on health behaviour, multiple phases of such interventions may be required.35 Messaging needs to be clear that axial SpA is a treatable condition and that early intervention can result in very good long-term outcomes.

Public health bodies have a critical role to play in developing public awareness campaigns. Public Health England’s Be Clear on Cancer campaign36, for example, aims to improve early diagnosis of cancer by raising public awareness of signs and/or symptoms of cancer, and encourages people to see their GP without delay. It provides a range of resources to support local and national social marketing campaigning. Despite the high prevalence of axial SpA (affecting 1 in 200 of the population) there has never been a similar national level campaign in axial SpA and without one we will not see a significant reduction in time from symptom onset to presentation in primary care.

To sit alongside a national awareness campaign, we propose that an online tool is created that can assist people in identifying their symptoms as potential axial SpA. In the US, for example, the Monster Pain in the AS website37 has a clear and effective online quiz which guides someone through a series of questions to determine whether their symptoms could be caused by inflammatory back pain and then advises whether they should see a healthcare professional.
**Ensure swift identification of potential axial SpA in primary care**

A recent national enquiry into axial SpA services in England\textsuperscript{38} found that only 15% of CCGs have specific programmes in place for educating primary care professionals about axial SpA. CCGs, Locality Networks, NHS Boards and Local Commissioning Groups have a critical role to play (as will new, emerging modes of care) in ensuring that adequate arrangements are in place for continuous professional development.

Educational materials are necessary but not sufficient. One of the themes to emerge from discussion at a 2019 meeting of the APPG on axial SpA is the need to create a critical mass of clinical champions in primary care so that axial SpA is higher on the clinical reasoning of GPs and other primary care professionals. We propose developing a Primary Care Clinical Champions Programme, initially on a pilot basis and with a particular focus in the first instance on First Contact Practitioners. It could be based on the Community of Practice model, cultivating an active community of primary care professionals with a special interest in axial SpA who can work together to create and share a body of knowledge, methods, tools and experience about how to ensure that patients with suspected axial SpA are identified at the first presentation and referred directly to rheumatology. The programme could include a leadership development component and the creation of a national/regional network to foster community-building and the exchange of ideas and good practice. It could also include training on quality improvement methods, such as those seen in NASS’s Aspiring to Excellence programme.

Popup tools on primary care information systems can be helpful in identifying patients with suspected conditions. We will support a tool for axial SpA which is currently in pilot form and, if successful, explore ways to achieve roll out.

Commissioners should be supported in their efforts to support early diagnosis of axial SpA. A return on investment tool would assist them in identifying and promoting appropriate interventions to reduce time to diagnosis.

We have already developed a referral template\textsuperscript{39} to help osteopaths and chiropractors recommend referral into rheumatology via GPs more easily. We will work with relevant bodies to achieve national rollout.
Ensure direct referral from primary (and secondary) care to rheumatology
The recent National Enquiry into axial SpA services across England found that only 21% of CCGs have a specific inflammatory back pain pathway in place. All CCGs, Locality Networks, NHS Boards and Local Commissioning Groups should have a clear and simple pathway in place to ensure direct referral as recommended by the NICE Guideline for Spondyloarthritis. We propose creating and sharing examples of best practice to assist these organisations.

Given the extra-articular manifestations of axial SpA, ophthalmology, gastroenterology, dermatology and surgical colleagues have a key role to play in screening appropriate patients for the presence of chronic back pain with inflammatory features and referring to rheumatology for assessment. We propose a programme to build new training resources and a peer to peer programme to target 40% of relevant secondary services across the UK within two years, working closely with rheumatology departments. This should be followed by a national review of ophthalmology, gastroenterology and dermatology services to assess the use of an Inflammatory Pain Pathway into rheumatology.

Likewise, pain clinics and musculoskeletal (MSK) triage services have a role in screening appropriate patients and referring them to rheumatology. Rheumatology departments need to have direct links with such services – we propose a national review to determine the extent of this.

Ensure timely diagnosis when the patient is referred into rheumatology
Radiologists have an important role in the diagnosis pathway. The nature and extent of current radiology training in axial SpA is unclear. We propose a national review as a precursor to the development of educational interventions, the promotion of routine implementation of imaging protocols and the promotion of tertiary centres offering virtual imaging to secondary care services.
**Consultation Document**

A Gold Standard Time to Diagnosis in Axial Spondyloarthritis

Our proposed high-level implementation plan is summarized in the following table, alongside recommended milestones:

<table>
<thead>
<tr>
<th>Focus</th>
<th>2021</th>
<th>2022</th>
<th>2023</th>
<th>2024</th>
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<tbody>
<tr>
<td><strong>Green</strong>: Actions for commissioners</td>
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<tr>
<td><strong>Blue</strong>: Actions for HCPs in primary care</td>
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<tr>
<td><strong>Orange</strong>: Actions for the third sector</td>
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<tr>
<td><strong>Red</strong>: Actions for HCPs in secondary care</td>
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<tr>
<td><strong>Purple</strong>: Actions for other bodies</td>
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</table>

**Primary care**

**Solution 1**: To help people with symptoms to recognize earlier that it might be axial SpA and then consult.

1. Implement a pilot primary care clinical champions programme.
2. Implement a return on investment tool for CCGs and others, and seek national endorsement.
3. Implement further roll-out of the primary care clinical champions programme.
4. Continue to support the programme.

**Primary care**

**Solution 2**: To ensure swift identification of potential axial SpA in primary care.

1. Implement a second phase of a national awareness raising campaign.
2. Create interactive tools to help patients identify potential axial SpA.
3. Continue to support the primary care clinical champions programme.

**Primary care**

**Solution 3**: To ensure potential axial SpA in primary care.

1. Implement a pipeline of a national awareness raising campaign.
2. Create public health bodies and workshops working with NASS, involving the public.
3. Continue to support the programme.

**Implementation milestones**

- [ ] Continue to support the programme.
- [ ] Implement a second phase of a national awareness raising campaign.
- [ ] Create interactive tools to help patients identify potential axial SpA.
- [ ] Implement a pipeline of a national awareness raising campaign.
- [ ] Create public health bodies and workshops working with NASS, involving the public.
- [ ] Continue to support the primary care clinical champions programme.
Focus 2021 2022 2023 2024

Solution 3: To ensure the patient is referred timely diagnosis when the patient is referred to secondary care services to assess use of an Inflammatory Pain Pathway into secondary care services to support and training to undertake a national review of rheumatology services to undertake a national review of rheumatology, ophthalmology, gastroenterology and dermatology.

Relevant national bodies to undertake a review of radiology training in imaging protocols and links with primary care services.

Relevant national bodies to ensure the pathway is in place from primary care direct to secondary care services.

Solution 4: To ensure a timely diagnosis when the patient is referred to secondary care services to assess use of an Inflammatory Pain Pathway into secondary care services to support and training to undertake a national review of rheumatology services to undertake a national review of rheumatology, ophthalmology, gastroenterology and dermatology.

Relevant national bodies to undertake a review of radiology training in imaging protocols and links with primary care services.

Relevant national bodies to ensure the pathway is in place from primary care direct to secondary care services.

Promote tertiary centres offering virtual imaging services to assess use of an Inflammatory Pain Pathway into secondary care services to support and training to undertake a national review of rheumatology services to undertake a national review of rheumatology, ophthalmology, gastroenterology and dermatology.

Relevant national bodies to undertake a review of radiology training in imaging protocols and links with primary care services.
References


The consultation is open until 4 September 2020. There are two ways to respond. You can either complete the questionnaire here and email it to goldstandard@nass.co.uk or fill in our online questionnaire.

If you have any questions about the programme or the consultation please email goldstandard@nass.co.uk.

This document should be cited as follows:


About Gold Standard Time to Diagnosis

Gold Standard Time to Diagnosis is led by National Axial Spondyloarthritis Society (NASS) in partnership with Norfolk & Norwich NHS Foundation Trust and RUH Bath NHS Foundation Trust.

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