2015 BNMS National DaTSCAN Audit

Report March 2017

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Summary

Background:
^{123}I-FP-CIT SPECT (DaTSCAN) is embedded in NICE management pathways for the diagnosis of parkinsonism and for the investigation of dementia with Lewy bodies. As important management decisions rest on the outcome of the DaTSCAN, it is important that investigation is performed to a high quality and that interpretation of the images is accurate.

Methods:
The 2015 UK and Ireland national clinical audit of DaTSCAN reporting was designed to assess the quality of studies performed and address the methodological issues noted in the 2012 report. UK centres providing DaTSCAN services were approached and invited to contribute data (images and reports) from 6 anonymised patients investigated at their centre. The data was read by experienced technical and clinical reviewers including random allocation to two independent clinicians blinded to the other reviewer's reports. To manage the administrative load, a web-based approach centred on the Hermes Cloud was constructed.

Results:
The number of participating centres increased (86 compared to 71 in 2012) although the proportion remained disappointingly low at 56% of the 152 centres approached. The names of the centres who participated are published on the BNMS website. For those centres that participated, the audit confirmed that the technical quality of the images was high with 96% of DaTSCAN images rated as excellent or satisfactory. The study also confirmed a high degree of agreement (88%) between the clinical review and the original clinical report. The independent reviewers agreed with the original report in 88% of cases. Disagreement with potential implications for diagnosis was noted in only 6% of cases. There was also good agreement between the two independent reviewers with perfect agreement in 84% of cases.

Conclusion:
For the centres that participated, the audit findings were re-assuring for both technical quality of the images and clinical concordance of the reports. Potential areas for improvement were noted and the results of the technical and clinical review were fed back to participating centres. Centres with discrepancies were offered technical support.

Contents

Acknowledgements

BNMS are grateful to GE Healthcare who sponsored the project and for their financial support without which this project could not have been undertaken.

BNMS wish also to thank Hermes Medical and in particular Steve Bloomer and Mikael Wallinder for the design and construction of the Cloud-based resource without which the audit project would not have been feasible.

Thanks also to the Office staff of the BNMS and in particular to Elena Gilbert who was responsible for the office administration of the audit project

BNMS are indebted to the technical and clinical reviewers who gave of their time and expertise freely to help undertake this clinical audit project.

Declarations

No conflicts of interest to declare.

Brian Neilly, December 2016

Background

The DaTSCAN remains in widespread use for the diagnosis of suspected Parkinson's disease and for the diagnosis of Lewy body dementia (DLB). Present NICE guidance (1) states 'Consider ^{123}I-FP-CIT SPECT for people with tremor where essential tremor cannot be clinically differentiated from Parkinsonism.' More recent NICE Imaging Pathway Guidance (October 2016) recommends the use of dopaminergic iodine-123-FP-CIT SPECT to confirm suspected DLB (2).

2012 DaTSCAN Audit

The British Nuclear Medicine Society (BNMS) completed a national audit of DaTSCAN technical quality and reporting of DaTSCANs during 2012 (3) and the results were presented at the annual meeting of the British and Irish Neurologists Group – Movement Disorders (BRING-MD). The results were encouraging in that the images were regarded as excellent or good quality in over 96% and that there was good concordance between the reviewers and auditors in 92% of the cases. While this result was regarded as encouraging, it was noted that only half of the potential centres in the UK and Ireland participated in the audit. The methodology was also regarded as suboptimal in that the review team was restricted to a small number of expert reviewers.

2015 DaTSCAN Audit

The 2015 audit aimed to achieve a higher uptake of participating centres and to address the methodological issues identified on the original audit. The previous audit was demanding in terms of the human resource use within the office of the BNMS. A further aim of the audit was to develop a software platform to facilitate the audit and to provide a template on which to base future national audits. To do this the help of Hermes Medical was enlisted allowing the use of the Hermes iCloud facility to upload and handle the data from participating centres.

Methodology

Centres

152 centres in the UK and Ireland were approached to participate. A co-ordinator was identified at each centre to oversee the centre's participation in the audit and to perform a gatekeeper role to maintain centre and patient anonymity and confidentiality. Each centre was assigned a unique identifier number known only to the centre co-ordinator and to the BNMS Office. Each patient from a centre entered in the study was given a unique number known exclusively to the centre co-ordinator.

Reviewers

A team of technical and clinical reviewers met ahead of the audit to agree the information and format of the images required and the scoring categories to be used.

Technical Reviewers
For the audit a technical reviewer was defined as an individual experienced in performing DaTSCANs and familiar with the strengths and weaknesses of the acquisition process. Four technical reviewers were identified and agreed to participate in the process of technical review of the studies. The data from a centre was scored by a single technical reviewer. A 10% sample of technical reviews was carried out by a senior reviewer for quality control purposes.

Clinical Reviewers
For the audit, a clinical reviewer was defined as a Nuclear Medicine clinician with experience of DaTSCAN reporting. All data from an individual centre was allocated at random to two clinical reviewers and taking account of the anticipated work load, twelve clinical reviewers were identified and took part in the study

Hermes Cloud web-interface.

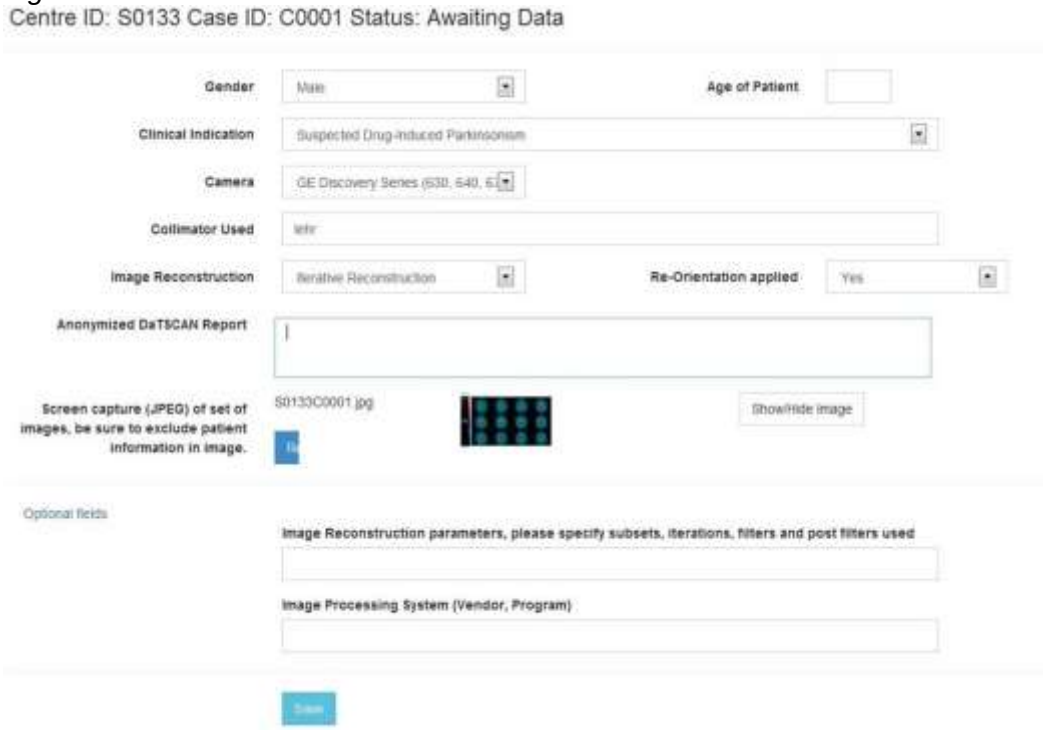
The present audit project involved a significant increase in the number of clinical reviewers and the need for the data from each centre to be allocated at random to two independent reviewers. To address the logistics of this it was necessary to devise a solution to minimise data-handling and administration by BNMS office staff. With this in mind, an approach was made to Hermes Medical for the design of a web-based interface centred on the Hermes Cloud. Key to the design of the cloud solution was the automation of the data upload, transfer, allocation and retrieval and the preservation of patient and centre anonymity.

A centre co-ordinator was invited to register for the audit by e-mail, generating a password-protected account and a unique computer-generated code for the centre co-ordinator and for the centre. The code details for centre and co-ordinator was known only to the centre co-ordinator and to the BNMS administrator. Participating centres were invited to upload the data relating to the first 6 consecutive scans undertaken at the centre from the 1st January 2014. At the request of one centre the data submitted was from 1 January 2015. Each patient from a centre entered in the study was given a unique number known exclusively to the centre co-ordinator.

Data Upload and Transfer

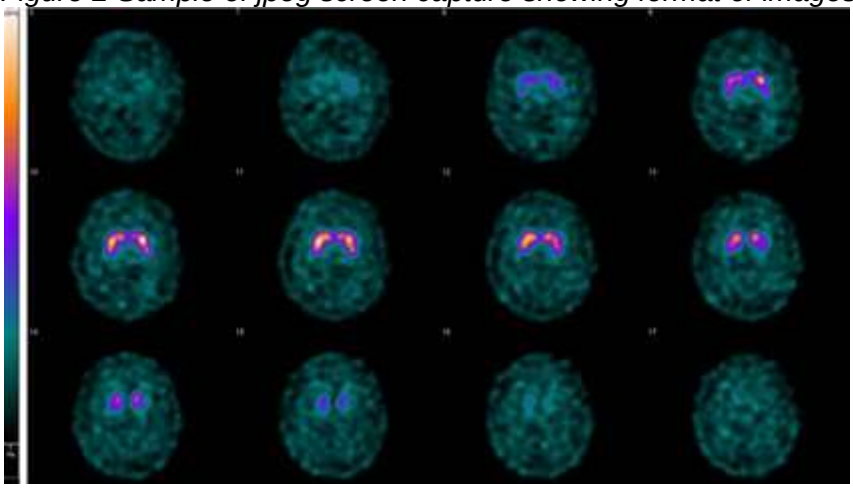
Each centre was asked to identify and submit data from 6 consecutive patients who had DaTSCANs at their centre from 1 January 2014. Each patient was assigned a unique study number known only to and recorded by the centre co-ordinator. A web-interface was designed to facilitate data upload, a sample screen shot of which is shown in Figure 1.

Figure 1 Screen shot of Web-Interface



As illustrated, data requested from each patient included gender, age, and clinical indication for the scan. Also requested were details of the gamma camera and collimator used, the image processing software and the reconstruction algorithm (FBP or IR) employed. Centre co-ordinators were asked upload a copy of the original DaTSCAN clinical report ensuring removal of all patient and centre-identifiable reference. The initial plan had been to request transfer of DaTSCAN images in DICOM format from each patient to allow reviewers access to the full image dataset. However, due to anticipated difficulty with this approach, it was agreed to restrict the request to a jpeg screen capture image incorporating 12 transverse slices, at least 6-8 of which should include the striatum of slice thickness 3-4.5 mm. For reference an example of a screenshot was provided to the centre co-ordinator (Figure 2). The preferred colour scales were given as: Hermes colour table 8; GE Systems: GE colour; Philips/ADAC systems: COOL; and Siemens Systems: warm metal. The centre co-ordinator was asked to ensure that all patient-identifiable and centre-identifiable data was removed from the header file of the jpeg image. Once the data and jpeg images from all 6 patients from the centre had been uploaded, the data was submitted to the audit.

Figure 2 Sample of jpeg screen capture showing format of images for review.



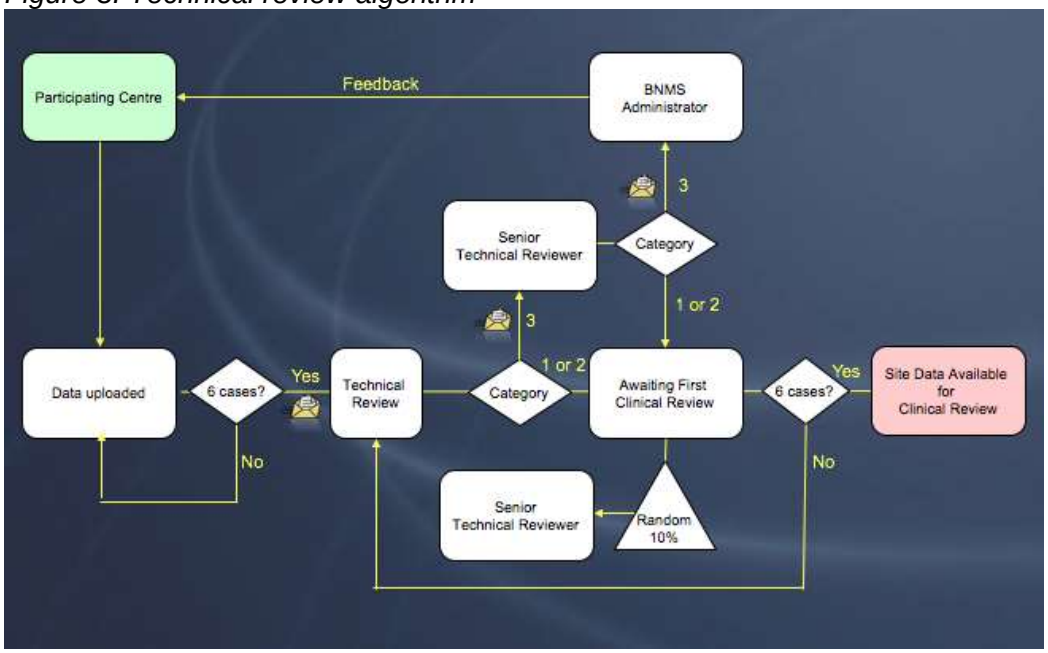
Technical Review

Technical review took place ahead of clinical review. Once the data from all 6 patients from a centre had been received, the dataset from that centre was allocated at random to one of four technical reviewers. Technical reviewers were provided with individual password-protected accounts and a unique identifier code. The images were categorized by the technical reviewer using pre-defined criteria (Table 1):

Table 1 Technical Review	Decision	Descriptor
Category 1	Excellent image quality	High resolution image which is correctly aligned and motion-free.
Category 2	Acceptable image quality	Satisfactory for reporting.
Category 3	Poor image quality, option to request resubmission of image(s).	Image quality unsuitable for reporting, requires feedback and resubmission of images. This may be due to noise, low counts, large radius or over-smoothed.

As shown (Figure 3), data from each centre proceeded to clinical review if the technical reviewer assigned a category of 1 or 2 for all 6 cases. A category 3 score for one or more images at a centre resulted in the cases(s) being made available for review by the senior technical reviewer and if necessary, the centre was approached to resubmit the data for the patient(s) in question.

Figure 3. Technical review algorithm



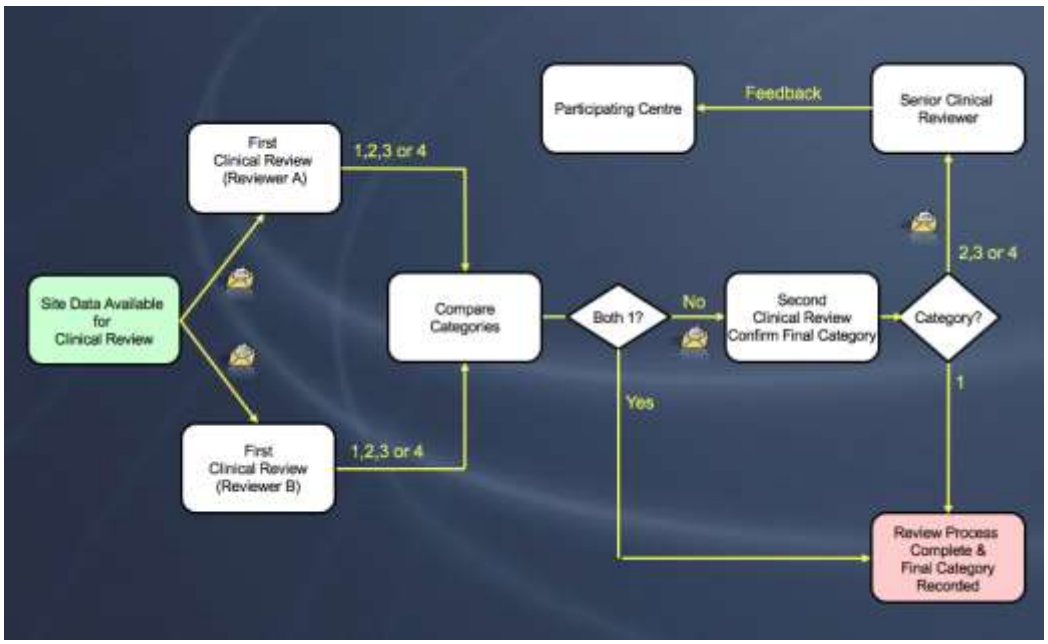
The random allocation process resulted in the four reviewers receiving a prompt to review the data from 26, 22, 22 and 14 centres. For quality control purposes, 10% of the dataset from the centres (8 centres) was reviewed by a senior technical reviewer.

Clinical review.

On completion of the technical review, the data from each centre was made available for the first clinical review (Figure 4). The images and data from each centre was randomly assigned to two clinical reviewers alerted by e-mail. Each clinical reviewer was provided with a password-protected account and a unique identifier to maintain anonymity. The two clinical reviewers assessed the data independently, blinded to the other clinical reviewer's assessment. Clinical review was undertaken using pre-defined outcomes as shown in Table 2.

Table 2 Category	Clinical Review Outcome	Descriptor
1	Concordant (including minor discrepancy) with the clinical report	
2	Discordant (with potential implications for diagnosis)	Action may be required involving feedback to the centre
3	Equivocal	Where category 1, 2 or 4 cannot be assigned. Examples are balanced striatal loss or asymmetry raising the question of striatal infarct
4	Un-interpretable	Poor quality image and/or lack of key data that prevent reasonable interpretation of the images.

Figure 4 Clinical review algorithm



Results

Centre Participation.

The audit was open for data entry for 6 months commencing in June 2015. Several reminders were sent and the deadline was extended and closed to recruitment in December 2015. In total 86 of 152 (57%) centres approached participated in the audit. This contrasts with 71 of 141 (50%) centres in the 2012 audit. The data anonymization process was checked at technical review and revealed that no image or dataset contained any patient-identifiable data. The images of one patient from a single centre included details of the centre of origin, but not details of the patient.

Demographic data and Clinical Indications

Data from 504 patients was submitted from 84 centres. Data from 2 other centres became available after completion of the data analysis. Of these 504 patients there were 289 males average age 68 years (24-93 years) and 211 females average age 71 years (44-93 years). The gender of 4 patients was not recorded, age 65 years (59-68 years).

The stated clinical indications for the request for the DaTSCAN scan were appropriate in all but one case (Table 3). The request for confirmation or exclusion of idiopathic Parkinson's disease or a Parkinson's plus syndrome were the majority indications and in line with national referral guidelines.

Table 3. Clinical Indication for DaTSCAN	N (%)
Confirmation or exclusion of Idiopathic Parkinson's Disease or Parkinson Plus Syndrome	393 (77.8)
Suspected Drug-Induced Parkinsonism	28 (5.5)
Suspected Lewy Body Dementia	63 (12.5)
Suspected Vascular Pseudo-Parkinsonism	18 (3.6)
Alcohol-related brain damage	1 (0.2)

REM Sleep Disorder	1 (0.2)
Total	504

Details of cameras and collimators in use are provided in Table 6 and 7 (Appendix 2).

Reconstruction algorithms

Filtered backprojection (FBP) was used in 274 cases and OSEM in 230 cases.

Data upload and transfer.

No difficulties were reported by the reviewers concerning the process of data upload, distribution, storage and retrieval.

Technical Review.

The images were categorised as excellent (Category 1) in 237 cases (47%), acceptable (Category 2) in 247 cases (49%), and of poor image quality in 20 cases (4%). In total the DaTSCAN images submitted from the centres were of excellent or of satisfactory quality in 96% of the cases. In cases that were further assessed by the senior technical reviewer, the number of category 3 assessments was less (9 versus 20). Reasons cited by the technical reviewers for the award of a category 3 score included low counts, over-smoothing of images, head movement, head tilt and the need for improved alignment. Examples of the technical review are shown in Figures 5 to 8 (Appendix 1)

Clinical Review

Of the 506 patients where data was submitted 462 underwent review by the two independent clinical reviewers as per the allocation process. In a number of cases there was only one clinical review and it was necessary to request a second clinical review following the data analysis. Table 4 shows the results of the summed paired assessments undertaken by the two independent clinical assessors. The results reveal a high degree of concordance between the clinical reviews and the original clinical report. In 88% of cases the reviewers agreed with the clinical report. In 6 percent of cases the reviewers did not agree with the original report. In the remainder of cases the reviewers did not think they had sufficient information to provide a definitive opinion.

Table 4 Report Category		**Total Reviews**	**Percentage**
1	Concordant	816	88
2	Discordant	52	6
3	Equivocal	27	3
4	Un-Interpretable	29	3
Total		924	100

Table 5 shows the result of agreement between the two independent clinical reviewers. This revealed perfect agreement in 84 percent.

Table 5*		Reviewer B				
Clinical Category		1	2	3	4	Total
Reviewer A	1	377	10	8	13	408
	2	19	7	5	2	33
	3	10	0	1	3	14
	4	2	2	0	3	7
	Total	408	19	14	21	462

* Perfect agreement 84%, weighted kappa 0.257: p<0.001 (reference 4)

In cases where the scores of the two independent reviewers were different or a score of Category 2 or greater was given, the data and images from that centre were allocated at random (Second Clinical Review) to a third clinical reviewer who determined the final clinical category for the scan. The third clinical reviewer was able to see the comments of the two independent reviewers. After this second review, the final categories for the scans were: Category 1, 394 (88%); Category 2, 24 5%; Category 3, 22 (5%); and Category 4, 10 (2%). The results of the technical and clinical reviews were fed back to participating centres.

The reasons provided by clinical reviewers for Category 2, 3 or 4 ratings included: failure to consider or mention in the report the possibility of a vascular lesion as the cause of asymmetry; increased non-specific binding raising the possibility of balanced loss; the absence of information about the side of symptoms or the presence or absence of cognitive decline and the failure to address in the report the clinical question proposed by the referral form. There were also a few examples where the clinical reviewers thought the scan was normal when it had been reported as abnormal. The reviewers stated that quantification, if available, would have been of value in a number of these cases where it was not possible to award a concordant score. Examples of the jpeg images and the reviewer's comments are provided in Appendix 1 (Figures 9-16).

Discussion

Large scale projects such as national clinical audit, involving data sharing between multiple sites and individuals, have both human and financial resource implications. Central to the design of the audit was the need for patient, centre and assessor anonymity and the requirement for random allocation of data to technical and clinical reviewers with minimal requirement for office administrator input. In the design of the project it was necessary that data entry and upload was straightforward and easy to use. Such a project would not have been feasible without a web-based automated approach that facilitated data entry, minimised data handling and provided automatic alerts at the various stages of the review process. The web-based approach using the Hermes Cloud proved to be easy to use and office-light, restricting the need for input by BNMS office administration. Before launch the project was road tested in several pilot centres allowing fine tuning of the web-interface and audit process. Few difficulties were encountered with its use. Upload, storage, allocation and retrieval of data worked well and patient anonymity was preserved in all cases. The identity of the centre was included on the image of one case but not the identity of the patient. Overall the web-based mechanism was thought to be a

success and offers a model that could be adapted for future projects of a similar nature.

The number of UK & Ireland centres who contributed data to the project was higher than in the 2012 audit (86 compared to 71) but the proportion of participant centres was low (57%) and only marginally greater than in the previous study. On this occasion, 152 centres were approached to participate, multiple reminders were sent and the deadline was extended for the submission of data. Formal feedback as to the reasons for centre non-participation in the study was not obtained on this occasion but anecdotal accounts suggest that departmental work-load and lack of priority were factors that were mentioned. The names of those centres that took part in the 2015 audit will be published on the BNMS website.

It is encouraging that nationally the quality of the images submitted remains high. As in the previous audit, the technical quality of the images submitted was rated excellent or good in 96%, the same as in the 2012 project. The images were considered to be of poor quality in only a minority (4%). The reasons cited by the technical reviewers included low counts, over-smoothing of images, the presence of un-corrected tilt and patient motion artefact.

The commonest indication for a DaTSCAN request remains the confirmation or exclusion of suspected idiopathic Parkinson's disease or a Parkinsonian Syndrome. The next commonest indication was for suspected Dementia with Lewy bodies (DLB). These indications for Datscan are in line with current national guidelines.

One objective of the 2015 DaTSCAN project was to address a perceived methodological flaw in the previous study which used only a small pool of expert reviewers. This study expanded the number of reviewers and employed a model of random allocation of data and images to two independent reviewers. It also provided a second clinical review phase to those cases where there was discordance between the two reviewers. The Cloud-based approach facilitated this approach and the data from 77 centres successfully completed the first and second independent review process. There was a significance and high degree of concordance between the two independent clinical reviewers with perfect agreement in 84% of the cases read. The findings support the idea that the overall agreement between the clinical reviewers and the original report was high as before (88% concordance).

Areas for improvement were identified by both technical and clinical reviewers. The technical reviewers noted confounding factors including low counts, over-smoothing of images, head movement, head tilt and the need for improved alignment. Clinical reviewers noted recurring themes such as the failure to consider vascular lesions as the cause of asymmetry, increased non-specific binding of tracer and the absence of key information in the clinical request form such as side of symptoms and the presence or absence of cognitive decline that might suggest DLB. Examples of these areas for improvement are illustrated in Figures 5-16 in the Appendix. Semi-quantification is becoming more readily available and this may help to resolve some of the areas of discordant reporting.

Comments made by the clinical reviewers observed that being restricted to a jpeg was suboptimal and did not permit variation in the background and target intensity nor the ability to scroll through the striatal images. Future studies

should give consideration as to whether it is possible to make the images available in DiCOM format.

References

1. NICE Guidelines. Parkinson's disease in over 20s: diagnosis and management

   https://www.nice.org.uk/guidance/cg35?unlid=139496838201698164044

2. NICE Pathways. Dementia diagnosis and assessment

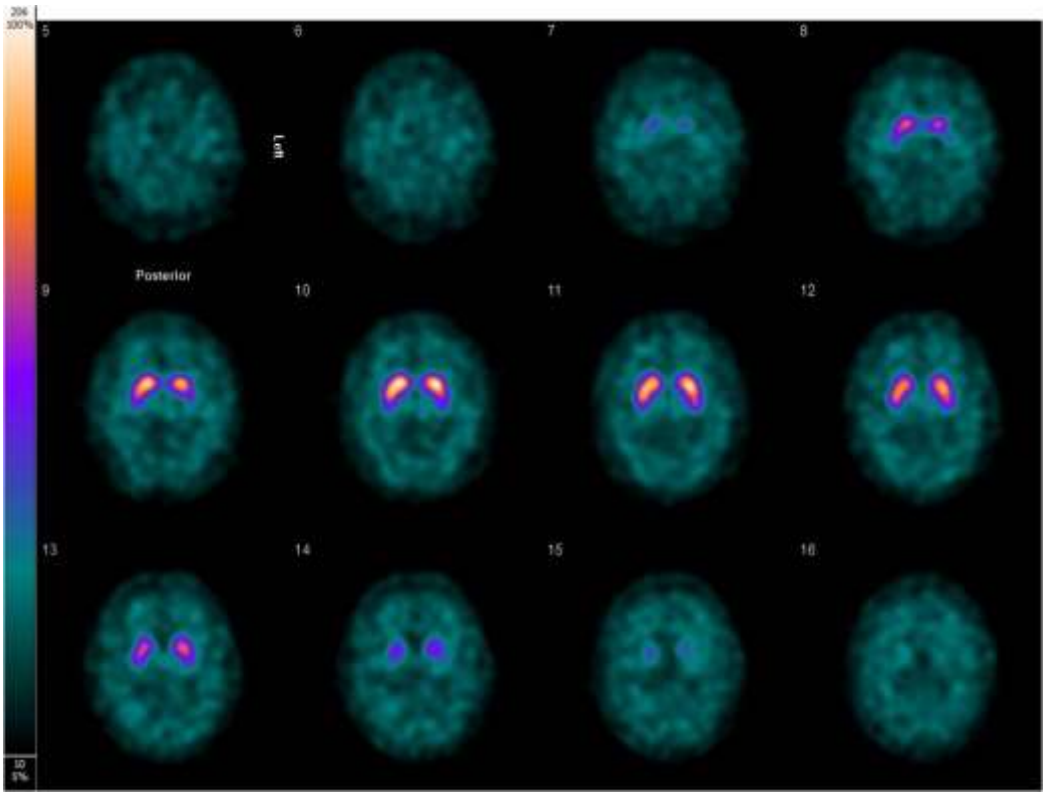
   https://pathways.**nice**.org.uk/pathways/**dementia**/**dementia**-diagnosis-and-assessment.pdf

3. BNMS 2012 DaTSCAN Audit (need source reference)

4. Landis J. and Koch G. [1977] The Measurement of Observed Agreement for Categorical Data. Biometrics, 33, 159-74.

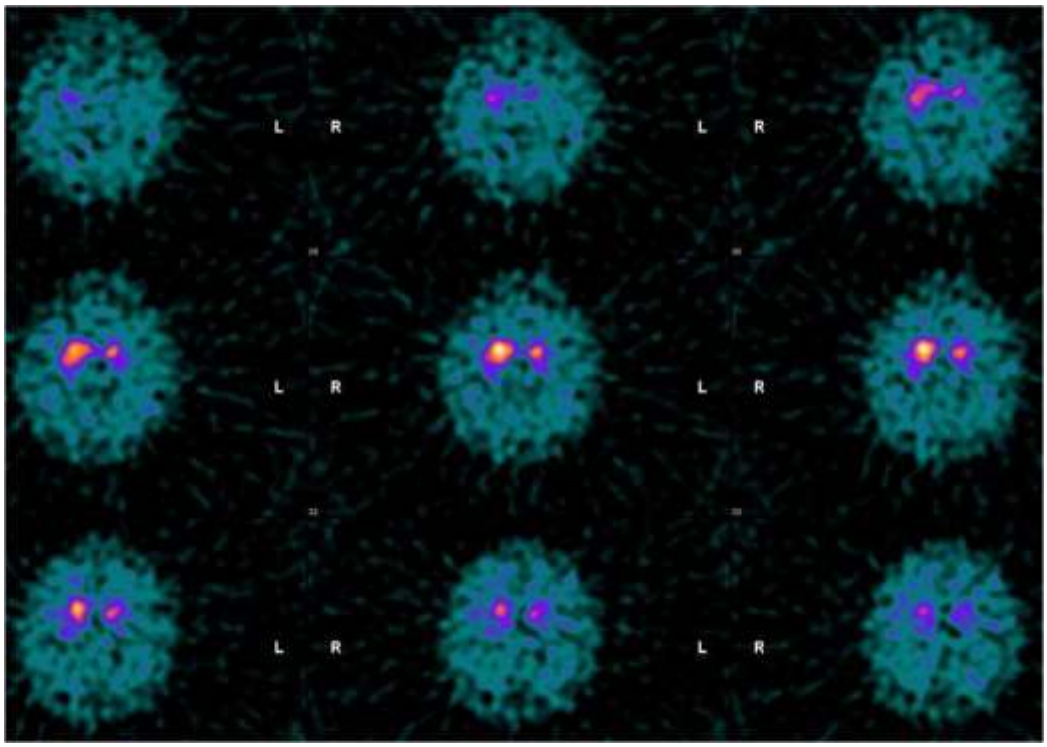
Appendix 1: Examples of Image Reviews

Figure 5



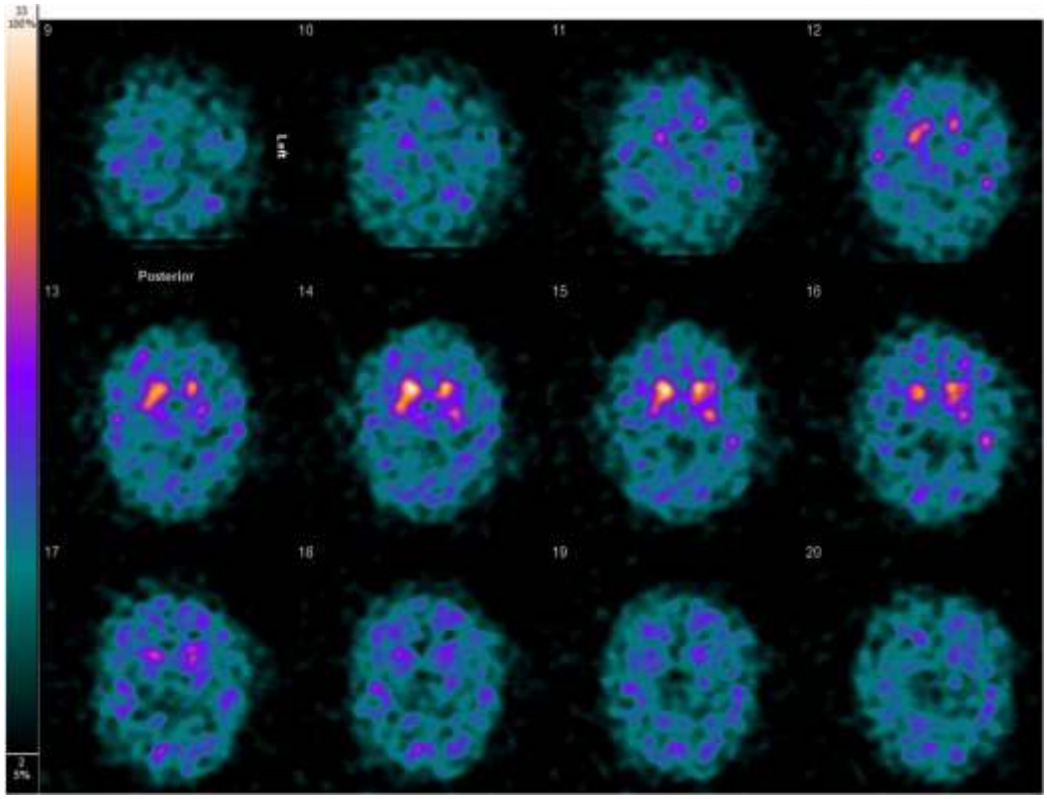
Technical Review, Category 1*. Example of excellent quality image.*

Figure 6



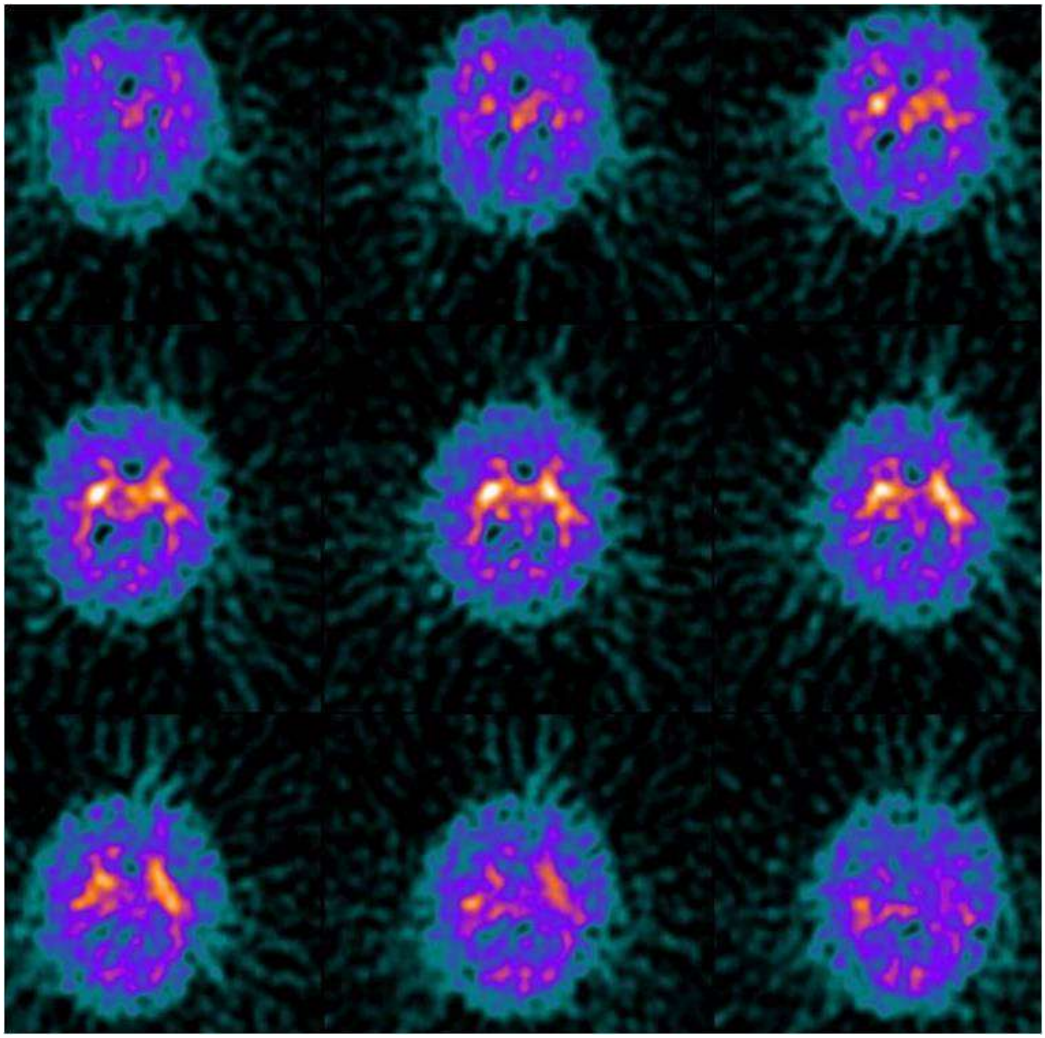
Technical Review, Category 2*. Acceptable quality image for audit purposes but thought to represent movement.*

Figure 7



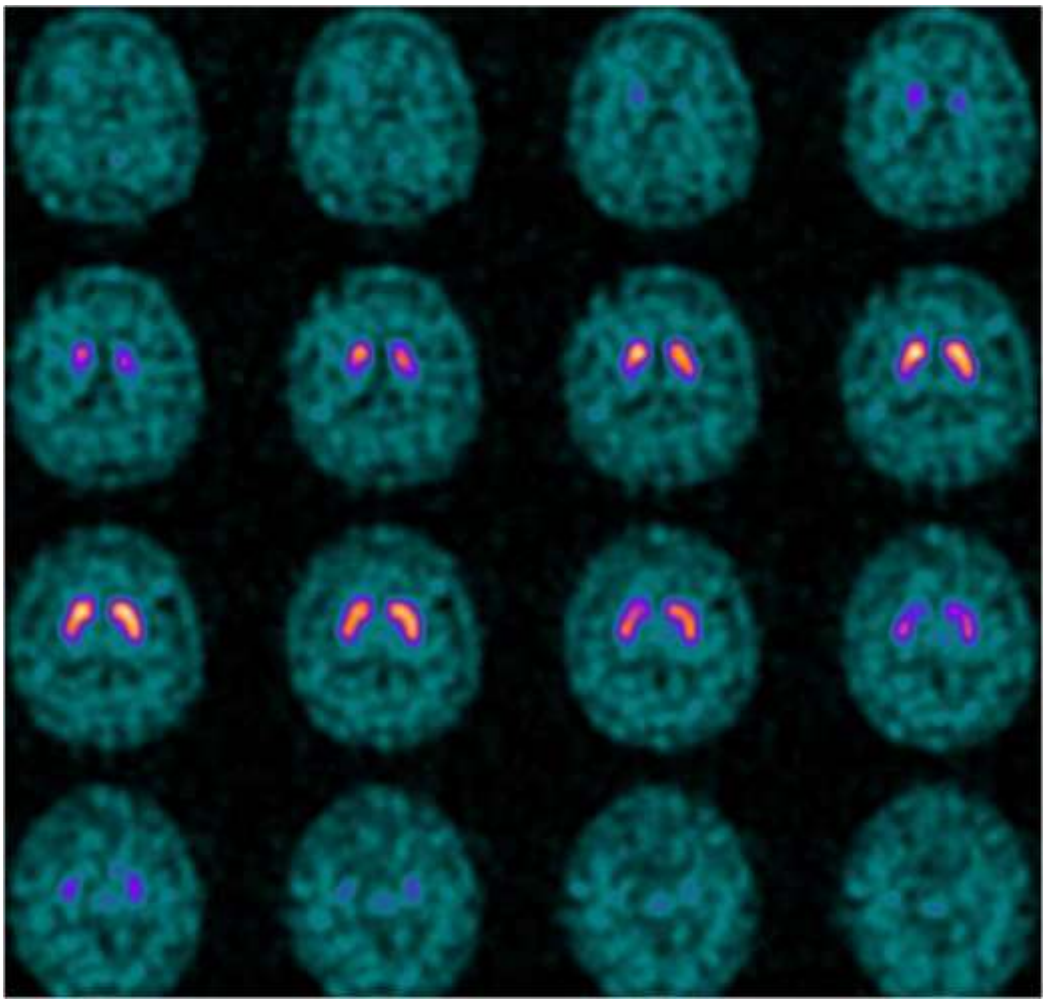
Technical Review, Category 3*. Count rate thought to be low.*

Figure 8



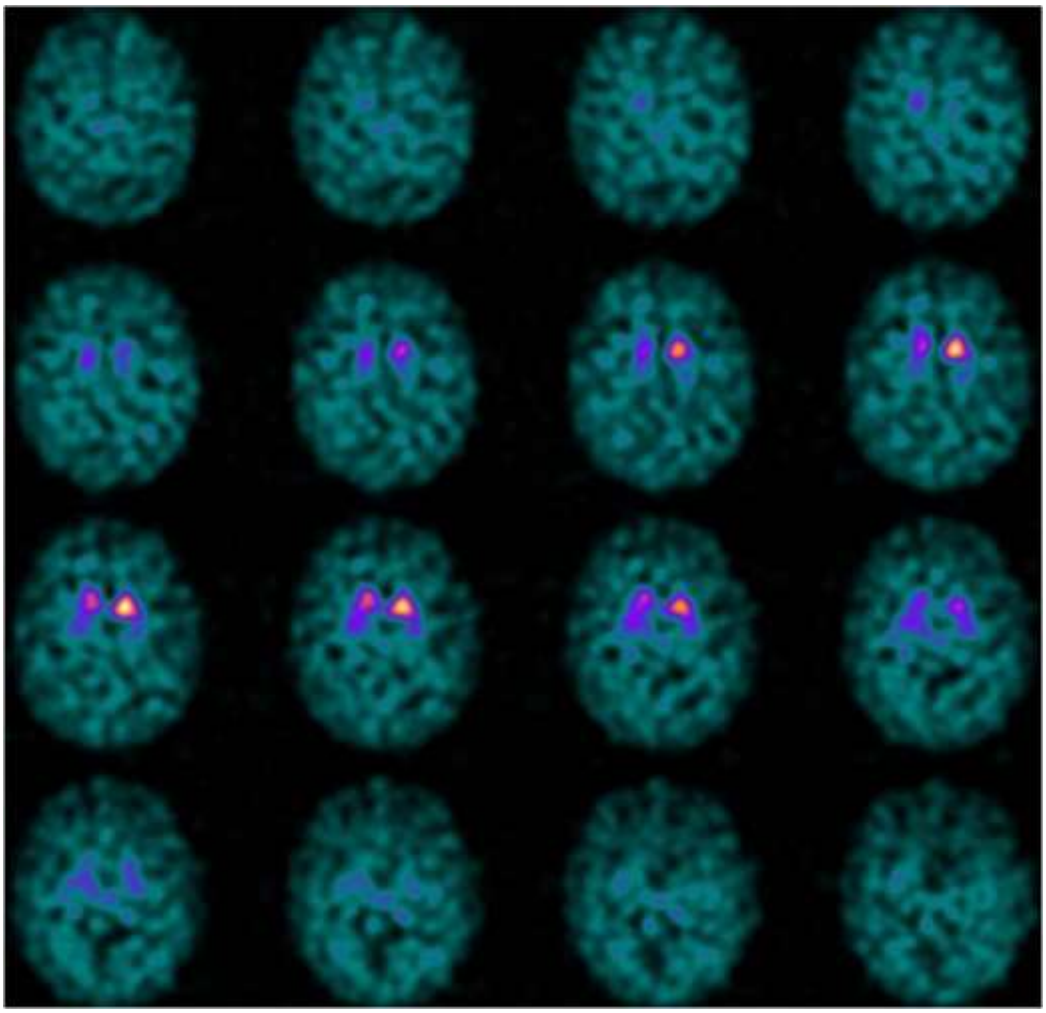
Technical Review, Category 3*. Images degraded by marked movement artefact.*

Figure 9



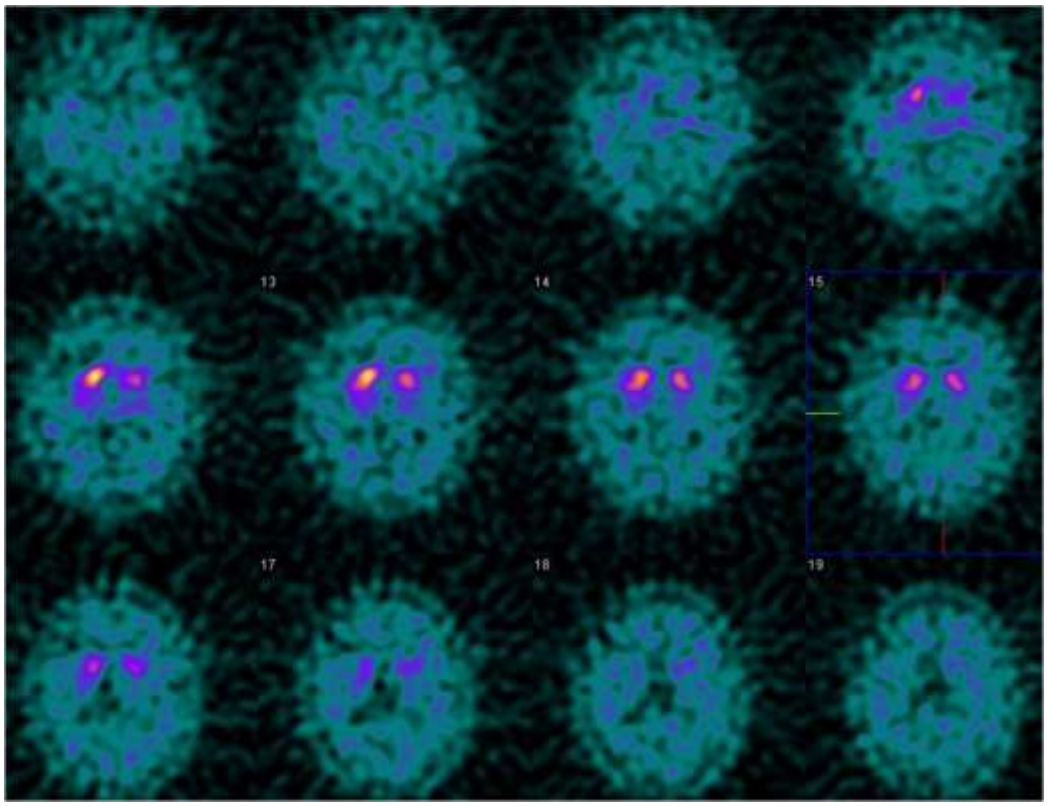
Clinical Review Category 1, normal scan*: Both clinical reviewers agreed with the clinical report that there is good uptake of tracer in the caudate nucleus and in the putamen bilaterally and with the conclusion that there is preserved pre-synaptic dopamine transport.*

Figure 10



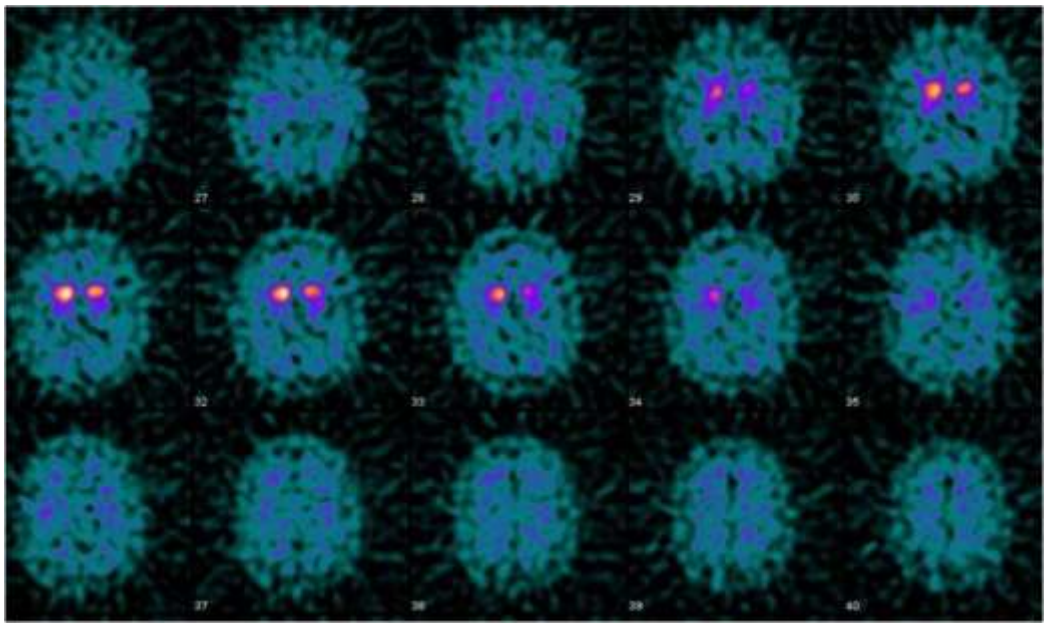
Clinical Review Category 1, abnormal scan*: Both clinical reviewers agreed with the report that there was reduced tracer uptake in both striata noting that the putamen was more severely affected than the caudate and that the reduced tracer activity was more marked on the right side.*

Figure 11



Clinical Review Category 1, abnormal scan*: Both clinical reviewers agreed with the report of reduced tracer activity in the striatum bilaterally but thought that it would have been more appropriate to mention the asymmetry of tracer uptake, higher on the right side.*

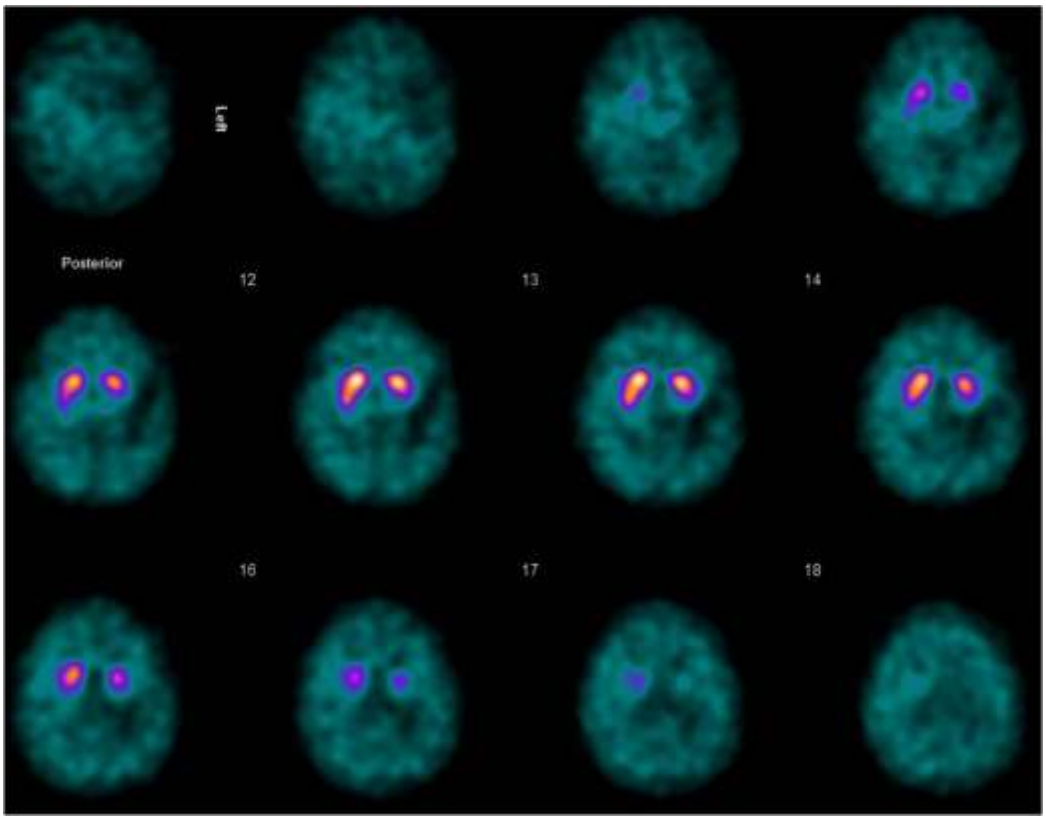
Figure 12



Clinical Review Category 1: Abnormal scan*: Both clinical reviewers agreed with the report that the scan was abnormal showing bilateral reduction in striatal*

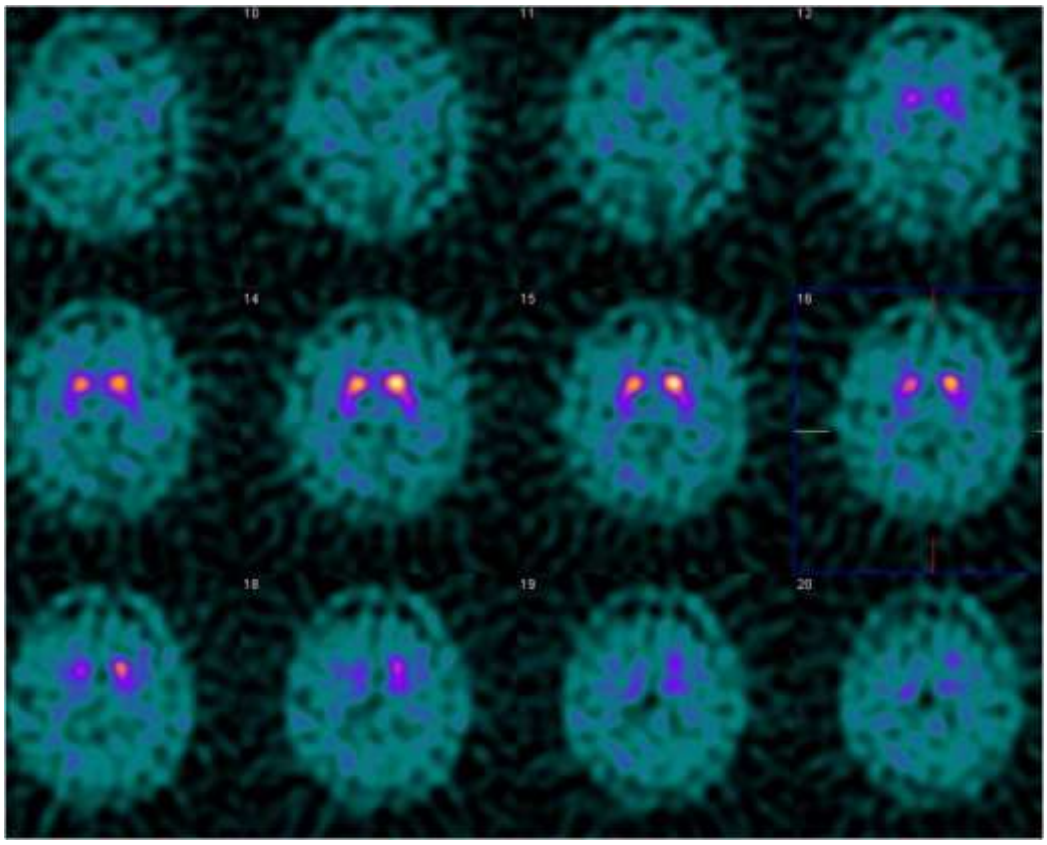
uptake but observed that it would also have been appropriate to mention that the findings were consistent with Dementia with Lewy Bodies (DLB) which was the reason for referral.

Figure 13



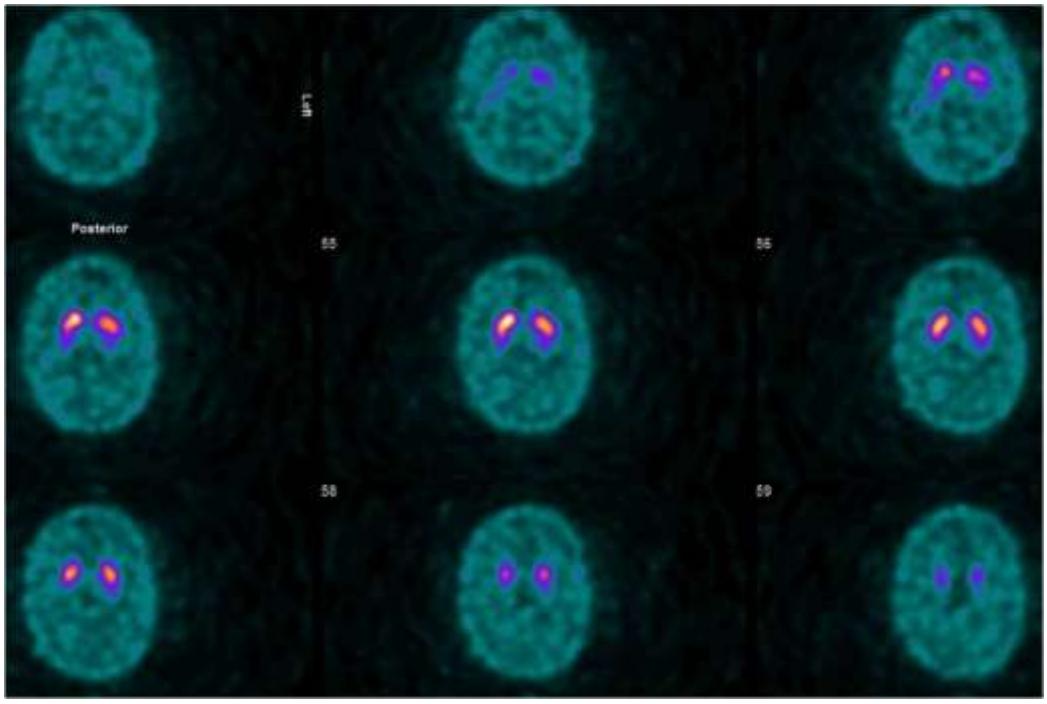
Clinical Review Category 2*: The clinical reviewers agreed that the study was abnormal with specific loss of uptake within the left lentiform nucleus but noted that due to the striking asymmetry, full interpretation would benefit from an up-to-date CT or MR to exclude an infarct centred on the left putamen.*

Figure 14



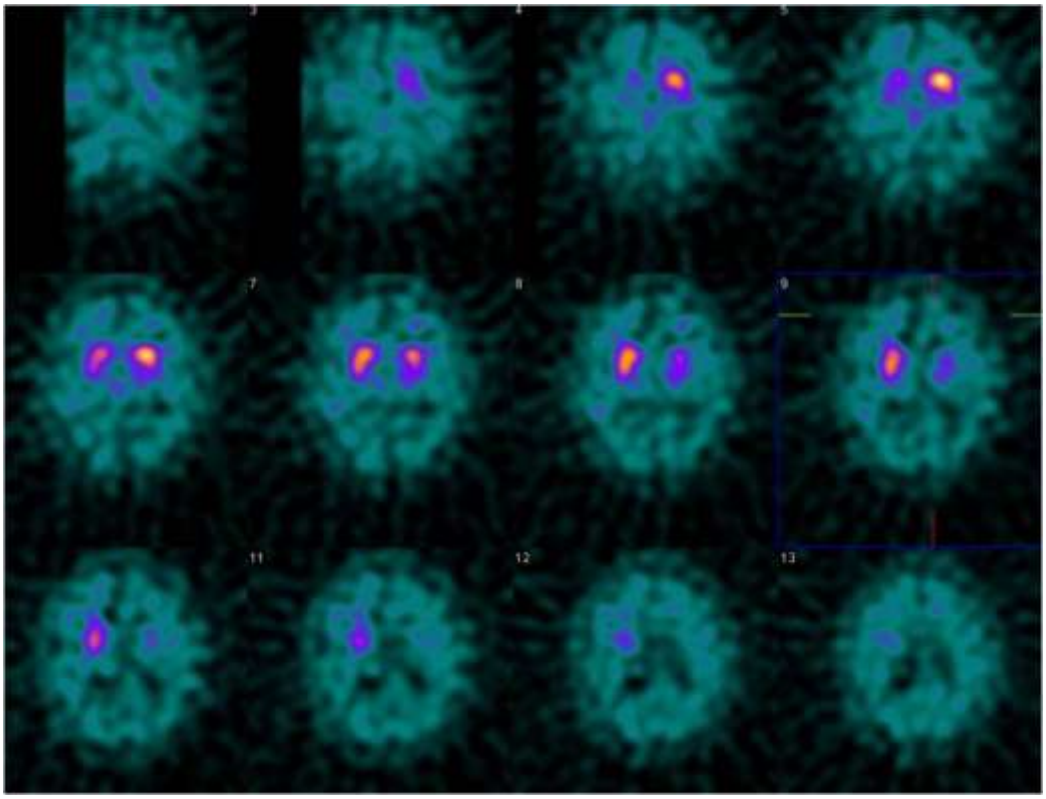
Clinical Review Category 2: *The report had concluded normal activity in the basal ganglia bilaterally but the clinical reviewers were of the view that there was decreased binding in the putamen bilaterally and increased non-specific binding suggestive of IPD or PPLUS syndrome. Further assessment using quantification was thought to be of value in this case.*

Figure 15



Clinical Review Category 3*. The clinical reviewers agreed there was minor asymmetry of uptake involving the left putamen but were uncertain whether this was real and thought that quantification would have helped in this case. It was also noted that information about the side of the symptoms would have been valuable in the interpretation of the findings. The report had mentioned that there was no vascular aetiology seen on a recent CT brain but there was no information about the side of the symptoms.*

Figure 16



Clinical Review Category 4. *The report had concluded that the scan was normal but the reviewers noted the presence of tilt which required correction. The review also raised the possibility of reduced tracer activity within the left putamen but that there was uncertainty because of the head tilt.*

Appendix 2: Camera Manufacturer and Collimator Use

Table 6 Summary of the information provided about camera manufacturer and collimator used.

Table 6 Camera Make	Numbers
ADAC Forte	6
GE Discovery Series	49
GE Infinia	112
GE Infinia Hawkeye	6
GE Millenium	6
GE Optima 640	6
Mediso four head	6
Philips Brightview	56
Philips IRIX	6
Philips Skylight	12
Siemens Symbia	184
Siemens ECAM	43
SMV DST	12
Total	504

Table 7, Information provided about collimator used

Table 7 Collimators used	Collimator
LEHR	444
LEUHR	6
LEAP	6
LEGP	6
HI-RES	6
Medium Energy Low Penetration	6
CHR	6
VXGP	12
High Energy	5
HIGH RESOLUTION	1
VP45 (LEHR)	6