Treatment of first-time traumatic anterior shoulder dislocation

(UK.TASH-D Study)

Study Protocol

This project was funded by the National Institute for Health Research Health Technology Assessment (project number 14/160/01).
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Full Study Protocol

NIHR HTA Commissioned Study: Treatment of first-time traumatic anterior shoulder dislocation (UK.TASH-D Study).

Version Control Table

Version	Date	Amendments
Version 1	December 2015	
Version 2	February 2016	Due to changes in CPRD services being offered in 2016 a GP questionnaire will now being used in Stage 1 of this study. See amendment section at end. Rather than obtain 100 sets of notes and use the validation algorithm in Appendix H, GP's will use a GP Questionnaire (Attached in Appendix I). This questionnaire follows the validation algorithm in Appendix H and has extra questions to ensure maximum data and information is obtained for subsequent analysis. CPRD quote a high 80% return rate with such questionnaires.

A. Lay Summary (Max. 200 words)

Traumatic anterior shoulder dislocation (TASD) is when the top end of the arm bone at the shoulder is forced out of the shoulder socket frontwards. This happens after injuries and is common in younger patients. It is very painful and the shoulder often stays dislocated until it is 'put back' in hospital. The joint can remain 'unstable' with more dislocations. The two main ways of treating this problem are physiotherapy and surgery. We still don't know the best choice and so it is important to know if surgery or physiotherapy after one dislocation is worthwhile in preventing further problems.
We should be able to answer this question using information that is already available within the NHS in two computerised systems called CPRD and HES. We have put together a research team with expertise in shoulder dislocation and expertise in studying these two databases. We plan to first check the coding of shoulder dislocations in the CPRD database by performing an initial assessment phase. If this is successful it means we can answer the question and we will then do a full analysis of the databases. We will then publicise our results widely so patients get the correct and optimum treatment.

B. Technical Summary (Max. 200 words)

Aims. To study the association between surgical treatment to no surgery and recurrence rates following first time TASD in young adults; and identify predictors of recurrent dislocations stratified by treatment.
Data sources: Clinical Practice Research Datalink (CPRD) linked to Hospital Episode Statistics (HES).
Population: 10,449 patients aged 16-35 years in CPRD with TASD and two years follow up.
WP1: Internal and external validation of shoulder dislocation coding and treatments within a routinely collected dataset (CPRD).

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WP2: Propensity score-matched cohort study using linked CPRD and HES. All events and outcomes will be collected using a pre-agreed list of READ CODES (CPRD) and OPCS 4.7 CODES (HES).
Exclusions: Surgery after more than one dislocation; instability treated with a rotator cuff repair or fracture surgery.
Intervention: Surgical repair within 6 months of first time TASD.
Control: non-surgical intervention.
Outcomes: Rate of re-dislocation, identified by codes in CPRD for 2 years after either treatment.
Sample size: 3065 with 656 expected total number of re-dislocations (90% power, 5% significance).
Statistical analysis: Propensity scores, Cox regression modelling and Rosenbaum bounds sensitivity analysis for ***Surgical versus non-surgical intervention on re-dislocation*****.** Multiple imputation methods, survival models and fractional polynomials for ***Predictors of recurrent dislocations.***

C. Objectives, Specific Aims and Rationale

Aim 1. To study the association between surgical treatment (compared to no surgery) and recurrence rates following a first episode of traumatic anterior shoulder dislocation (TASD) amongst young adults. **Aim 2**. To identify clinical predictors of further recurrent dislocations in young adults with traumatic anterior shoulder dislocation stratified by surgery and no surgery.
Objectives: Following the HTA commissioning brief, we plan to use routinely collected observational datasets (Clinical Practice Research Datalink (CPRD) and Hospital Episodes Statistics (HES)) to answer the research questions above. The size of routinely collected data in UK primary care (CPRD) and secondary care (HES) offers rapid observational data to uncertainties about treatments in an affordable and generalisable manner. We have planned a propensity score-matched cohort study, with the intention to minimise confounding. Propensity score matching is considered one of the best methods available to approximate to any results obtained from randomised controlled trials. To ensure further value for money and to confirm the ability of these datasets to answer this very specific commissioned question, we plan a two stage approach through Work Packages 1 and 2.
Work Package 1: Data Validation of shoulder dislocation coding and treatments within a routinely collected dataset (CPRD). Work Package 2: Population based cohort study using routinely collected datasets (CPRD and HES).
Having run feasibility counts in CPRD and there are 26,534 patients with shoulder dislocations in the database. We expect at least 10,449 to be TASD in 'young' patients aged 16-35 years of age [7] indicating a very substantial dataset to answer this commissioned call.

D. Background

This project and study has been commissioned by the HTA and as such has already been deemed necessary. We can confirm that since the commissioned call there have been no published systematic reviews, or RCTs that answer the commissioning brief.
Shoulder joint dislocations are the most common joint dislocations seen in hospital A+E departments (8.2-17 cases per 100,000 population/year) with 95% of traumatic gleno-humeral dislocations being anterior [15]. Traumatic anterior shoulder instability can carry significant morbidity. Some in the clinical community still quote high re-dislocation rates of 85% [16] and 92% [17] despite more recent larger population studies. A small but highly cited Swedish population study was conducted by Hovelius [18]. This prevalence study was in a random sample of 2092 people aged 18 to 70 years. 1.7% of patients reported a history of dislocation. There was a male to female ratio of 3:1 overall but this ratio varied with age being 9:1 in the 21 to 30 years age group. Hovelius also looked at recurrent dislocation trends

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which were more common in younger adults. A 10 year follow-up identified 66% of patients aged between 12 and 22 years at the time of their first dislocation had one or more further dislocations but only 24% had a recurrence in those aged between 30 and 40 years [19]. In 2010, Zacchilli et al [20] examined the incidence of traumatic shoulder dislocation in the whole USA population. They reported an overall adjusted incidence of more than double of what was previously believed (23.9, 95% confidence interval (CI) 20.8 to 27.0, per 100,000 person-years). Seventy-eight per cent of dislocations occur in men (overall incidence rate in males: 34.9 per 100,000 person-years, 95% CI 30.1 to 39.7; in females: 13.3 per 100,000 person-years, 95% CI 11.6 to 15.0).
It was in 1923 that Bankart described an anterior labral avulsion from the glenoid during dislocation and so developed the enthusiasm for surgical treatments to correct what is deemed a structural problem. While current management options still encompass a variety of non-operative treatments (slings, splints and physiotherapy) [21], there are frequent operative treatments which are either soft tissue reconstructions (eg. Bankart labral repair) or bony procedures (eg. Corocoid process transfer) [6]. These procedures can be performed either by arthroscopic (keyhole) or open surgery but even when pooling results from 4 RCTs in a systematic review there remains a lack of evidence and debate as to whether open or arthroscopic surgery is more effective, exactly when surgery is needed, and whether surgery is superior to physiotherapy alone [6, 22]. This is especially debated after first time TASD and we still have poor UK published data on age and gender prevalence's and impact on patients lives and occupations. Our proposal aims to provide evidence and answers to patients, primary and secondary care clinicians as well as commissioners in order to optimize treatment pathways of care for this common condition.

E. Study Type

Conceptual Framework: A cohort study using large routinely collected datasets will be conducted to study the association between surgical treatment (compared to no surgery) and re-dislocation rates following first time traumatic anterior shoulder dislocation (TASD) in young adults. Analysis will also be undertaken to identify predictors of re-dislocation.
Study Design: This study design is in two phases requiring 2 Work Packages (WP). WP1 will test the internal and external validity of CRPD coding in identifying patients with TASD and any treatments. 100 random sets of CPRD notes of patients aged 16-35 years with first time TASD will be analysed for validity of coding and completeness of relevant data. Age-gender prevalence rates of the data set will also be compared to published age-gender prevalence rates from other settings.
WP2 is the main study and is a population based propensity score-matched cohort study using the CPRD and HES datasets. This is one of the best designs and approaches now available in dealing with confounding by indication present in observational data. The propensity scoring approach will ensure that each patient receiving surgery for TASD is matched to a comparable non-surgical control.

F. Study Design

We will use CPRD and the Hospital Episodes Statistics (HES) as our data sources. However, with no previous reports on the validity of shoulder dislocation coding in CPRD, we are conducting the study in two phases (Work Packages 1 and 2). Before conducting the population based cohort study (WP2), we plan to validate these cohorts through WP1. A validation algorithm is included in appendix H. We plan a CPRD internal validation notes review and we will also test the sensitivity and specificity of these codes in CPRD. An external validation of the age/gender prevalence rates in CPRD for this condition will also be performed. There will then a 2 month stop gap during which a report and updated analysis plan will be submitted to the HTA justifying progression to WP2.

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CPRD Internal Validation. 100 random sets of notes of patients aged 16-35 years with first time TASD will be identified in CPRD. First time TASD will be those patients with at least two years of data (washout period) before a first time entry read code for shoulder dislocation and with at least a further two years of follow up coding. These notes will be assessed for: use of shoulder dislocation codes for traumatic dislocation; confirming first time shoulder dislocation; confirming traumatic cause; and assessing the subsequent codes used for further events. Physiotherapy referral codes regards physiotherapy will also be assessed especially in terms of data on frequency of therapy, place of therapy (hospital or community) or type of therapy. Overall, data quality and completeness will be assessed using the GP questionnaire service (Appendix I) provided by CPRD. This questionnaire is based on the validation algorithm in Appendix H. Those risk factors that may play an important role as predictors of further re-dislocation and that are identifiable in CPRD will also be recorded. This analysis would ascertain which factors are reliably identifiable in CPRD and inform any formal analysis in WP2 regards future predictors.

Prevalence Rates (External Validation). We will compare age-gender prevalence rates of first time dislocators identified in our study with those of similar studies in other settings [7, 20]. This will externally validate GP and primary care coding of this condition. This external validation study will itself provide first time age and gender prevalence data on traumatic anterior shoulder instability in the UK.

During work package 1, if the analysis of the notes indicates that first time dislocation coding and recurrent dislocation coding is poor then the study cannot proceed and will be STOPPED (Red Light). To quantify this if during our review of coding and free text entries on patients with first time TASD, if the positive predictive value of CPRD codes is > =75% (% recorded according to READ/OXMIS codes that are confirmed in the free text search) then we will continue to Stage 2 (Green Light). We would also take this opportunity to estimate the sensitivity of TASD coding by using the algorithm on CPRD codes of alternative coding diagnose to include, but not limited to, shoulder pain, rotator cuff disorder, shoulder OA.

Main study (WP2): The main study (WP2) will be a population based propensity score-matched cohort study using CPRD and HES collected datasets. The cohort of participants in this study will be young adults (aged 16–35 years) with traumatic anterior shoulder dislocation (TASD) with at least 2 years data entry in CPRD before the their first shoulder dislocation code and at 2 years follow up from their first dislocation code entry in CPRD. All events and outcomes will be collected using a pre-agreed validated list of READ CODES (CPRD) and OPCS 4.7 CODES (HES). These codes are listed in the appendices and have already been identified. They will be further validated and informed by WP1. The first read code entry in CPRD for shoulder dislocation will be defined as the 'first dislocation'. These codes will then be routinely linked to patients and to HES.

The ***Intervention group*** will be patients in CPRD with first time TASD who underwent shoulder stabilisation surgery after their first dislocation (early surgical repair in this NHS context will mean 'a decision to treat surgically after the first TASD' and receiving surgery within 6 months). This means linking HES data to CPRD data in such a way that a HES surgical OPCS 4.7 code is seen to occur after a single first dislocation code in CPRD (without further dislocation codes) before that surgical date. The timelines between first dislocation codes and OPCS 4.7 codes will be recorded. The ***Control group.*** While the most desirable control group would be physiotherapy, it is possible that WP1 will reveal that free text notes and referral codes on physiotherapy will be lacking and not reliable. If this is the case then conservative care will be defined as 'non surgical intervention' with no linked OPCS 4.7 surgical shoulder codes producing a control cohort of patients whose first time shoulder dislocation has been treated non-operatively. If however free text entries and referral codes for physiotherapy are reliably present in CPRD then conservative care will be physiotherapy identified by physiotherapy referral codes after a first time TASD code. Any subsequent dislocation codes or OPCS 4.7 surgery code will be recorded.

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In order to provide further valuable information for decision makers with regards to efficient treatment care pathways for TASD, the CPRD and linked HES data will also be used to estimate the economic burden associated to the management of this condition. GP practice consultation and referral as well as prescription data will be extracted to build an estimate of primary care resource use, converted into direct healthcare NHS costs by applying current unit prices as reported in the NHS electronic drug tariff and the Unit Costs of Health and Social Care publication. Consultations with GPs are expected to be recorded most accurately whilst the accuracy of those with physiotherapists, highly relevant for the 'conservative care' group, will be established during WP1, as explained above. Estimates of primary care costs will be complemented by outpatient secondary care costs obtained from the Healthcare Resource Group codes reported in HES records. Both primary and inpatient secondary care cost estimates associated to the management of patients with TASD following first dislocation and subsequently split according to whether they received surgical or conservative treatment will provide an overview of costs, from the perspective of the NHS, largely unexplored to date and essential for further studies potentially exploring the cost-effectiveness of the surgical intervention.

G. Sample Size

Using data from a Cochrane systematic review comparing surgical to non-surgical treatment for acute TASD [6]; from the pooled results 3/58 patients in the surgical arm had subsequent further surgery (5.17%) compared to 17/61 in the non-surgical arm (27.9%) at a minimum follow up of 2-years (Risk Ratio 0.22, 95% CI 0.08 to 0.64). The large effect size is set in the context of the pooled results of 3 RCTs with uncertainty around the true size of the effect outside of a clinical trial setting in routine general practice. Conservatively, we would look to detect a smaller difference in subsequent surgery within 2-years of 25% in the non-surgical group, compared to 20% in the surgical group (an absolute difference of 5%). A 2-sided log rank test for equality of survival curves, with 90% power at 5% significance level (alpha), where outcome is time to re-dislocation, with an anticipated 25% re-dislocation rate in the non-surgical control group compared to a 20% in the surgical group (equivalent to a hazard ratio of 0.78), allowing for 10% loss to follow up and assuming equal group sizes, we require a total sample size of 3065 with 656 expected total of re-dislocations. There are 26,534 patients in CPRD with recurrent anterior shoulder dislocations, and at least 10,449 of these patients will be aged 16-35 years with TASD [7]. The study will therefore be adequately powered***. See flow diagram in appendix for estimation of numbers.***

H. Data Linkage Required (if applicable)

Data linkage and data management for our proposed study involves 2 different data sources (CPRD and HES). They need to be linked to answer the aims of WP2 as stated above. We have therefore included co-applicants with extensive experience in the use of linked datasets. The data management needed to produce a final working dataset will be carried out by a senior data manager at Oxford with expertise in such procedures. Under supervision from the application team, the data manager will develop ad-hoc code in Python and SQL to produce a dataset that can be analysed using standard statistical packages such as Stata.

I. Study Population

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This commissioned call is directed at 'younger adults'. From age 40 years onwards instability and dislocation is associated with rotator cuff tears and the pathology and outcomes are different. Rotator cuff tears are highly rare below age 35years and so or young target population will be patients aged 16-35 years in CPRD with a first time TASD who underwent stabilisation surgery within 6 months of their first dislocation. We require a total sample size of 3065 with 656 expected total of re-dislocations. There are 26,534 patients in CPRD with recurrent anterior shoulder dislocations, and at least 10,449 of these patients will be aged 16-35 years with TASD [7].

Inclusion criteria: Patients aged 16-35 years of age with a first time traumatic anterior dislocation (TASD); patients that can be linked by CPRD and HES; minimum two year follow up period in CPRD.

Exclusion criteria: Surgery after more than one dislocation; instability treated with a rotator cuff repair or fracture surgery. We will also exclude:

- Patients aged 16-35 years with first time TASD who cannot be linked by CPRD-HES
- Patients with less than two year follow up in CPRD
- Surgery after more than one TASD
- Instability treated with rotator cuff repair surgery or fracture surgery.

J. Selection of comparison group(s) or controls

The ***Intervention group*** will be patients in CPRD with first time TASD who underwent shoulder stabilisation surgery after their first dislocation (early surgical repair in this NHS context will mean 'a decision to treat surgically after the first TASD' and receiving surgery within 6 months). This means linking HES data to CPRD data in such a way that a HES surgical OPCS 4.7 code is seen to occur after a single first dislocation code in CPRD (without further dislocation codes) before that surgical date. The timelines between first dislocation codes and OPCS 4.7 codes will be recorded. The ***Control group*****.** While the most desirable control group would be physiotherapy, it is possible that WP1 will reveal that free text notes and referral codes on physiotherapy will be lacking and not reliable. If this is the case then conservative care will be defined as 'non surgical intervention' with no linked OPCS 4.7 surgical shoulder codes producing a control cohort of patients whose first time shoulder dislocation has been treated non-operatively. If however free text entries and referral codes for physiotherapy are reliably present in CPRD then conservative care will be physiotherapy identified by physiotherapy referral codes after a first time TASD code. Any subsequent dislocation codes or OPCS 4.7 surgery code will be recorded.

K. Exposures, Outcomes and Covariates

As part of this application, we have performed a consensus survey of specialist shoulder surgeons and shoulder physiotherapists who are all members of the British Elbow and Shoulder Society. Saturation point and a list of predictors was reached rapidly and this list is tabulated in Appendix E and highlights the risk factors (and covariates) deemed most important. It is unlikely that all of these will be available from routinely collected national datasets but our study design will allow us to confirm through WP1 those factors that are reliably collected and that can be used for full analysis in WP2.

L. Data/ Statistical analysis

The association of surgical versus non-surgical intervention on subsequent re-dislocation within 2-years. The primary outcome of interest is the time from a first time traumatic anterior dislocation to subsequent re-dislocation within 2-years. The exposure of interest is whether or not a patient received shoulder surgery. In randomized controlled trials each person has

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an equal probability of being in a treatment or control group. Observational study designs are limited by an inherent imbalance of both known and unknown confounders making some patients more likely to receive surgery than others. As the type of surgery received is not randomly allocated in our study, confounding by indication will be accounted for by using propensity score matching methods. Use of these methods for the assessment of causality in epidemiological studies has been previously described[1]. The propensity score represents the probability that a patient received the intervention (surgery). A logistic equation is fitted where the outcome is surgical intervention versus non-surgical; and any covariates are introduced as potential confounders of subsequent dislocation. We have already identified an expert consensus list of all potential confounders of interest (Appendix E)

Propensity scores are used to match each patient receiving surgery to comparable non-surgical controls using a caliper width of 0·2 standard deviations of the logit of the propensity score[2]. This is a standard method for minimizing confounding by indication, which not balances observed baseline characteristics in both surgical and non-surgical groups, but also eliminates surgical patients with no comparable controls[3].

Immortal time bias is a common issue in epidemiological studies, where the event of interest cannot occur for a certain time span. In the case of this proposed study immortal time bias would occur due to the definition of exposure, where in the time from first dislocation till receipt of surgery those in the 'surgical arm' cannot have the outcome by design otherwise they would have been classified as non-surgical. To avoid the problem of immortal time bias, we will use time varying exposures, where in a survival analysis the time period previous to the index date of surgery is reclassified as non-surgical for those in the surgical intervention group.

Matched surgical patients and their non-surgical controls will then be included in a Cox regression survival model to describe the association between receipt of surgery and time to subsequent dislocation within 2-years. The model is stratified on matched sets, to allow for the correlation between matched pairs of surgical patients and controls. As clustering exists within the data (patients nested within GP practices), a multilevel survival model will be fitted by extending the Cox regression model to include a frailty term with a Gaussian distribution[8]. This will allow adjustment for evidence of unexplained variation across GP practices. To assess the potential effect of unmeasured confounders we will conduct a Rosenbaum bounds sensitivity analysis[9]. This provides an estimate of the magnitude of hidden bias that would have to be present to explain the associations actually observed. The proportional hazards assumption will be assessed using Shoenfelds residuals. Kaplan-Meier plots will be used to estimate the probability of survival up to 2-years in surgical and non-surgical groups.

<u>Identifying predictors of recurrent dislocations</u>

Using the CPRD-HES linked dataset we will develop a prediction model to identify patients at increased risk of subsequent re-dislocation. Potential risk factors will include all those described above. The cumulative effect of missing data in several variables often leads to exclusion of a substantial proportion of the original sample, causing a loss of precision and power. To overcome this bias we will use multiple imputation methods, which allows for the uncertainty about missing data by creating several plausible imputed datasets and appropriately combining their results [10, 11].

Survival models (Cox regression) will be used to identify risk factors associated with time to re-dislocation. Backward selection methods will be used to identify risk factors and shrinkage methods applied to adjust for over fitting. Continuous predictors will be examined using fractional polynomials and clinically plausible interaction terms will be tested for inclusion (specifically whether the predictors differ in the surgical and non-surgical intervention groups). For internal validation of the model we will use a combination of multiple imputation and bootstrapping[12-14].

Performance of the model will be assessed in terms of calibration and discrimination[11, 23] Calibration measures how closely predicted risk agrees with observed outcomes, which will

be assessed graphically and quantified by estimating the calibration slope and intercept. Discrimination is the ability of the model to differentiate between people who have a re-dislocation versus those who don't. Discrimination will be assessed by calculating the area under the ROC curve, or the equivalent concordance (C) index.

Sensitivity Analysis:
In order to minimise Berkson's bias in the analysis of the association between surgical repair and re-dislocation, we will explore the hazard function for both exposed (i.e. those undergoing surgery) and unexposed participants. If this suggests such a bias, then we will run a sensitivity analysis excluding patients with early re-dislocation following surgery, which is a very uncommon event.

M. Plan for addressing confounding

As in the section above it is vital to deal adequately with confounding by indication. The team of applicants includes academic experts that have been leaders in the development of propensity scoring and prognostic modelling. In randomised controlled trials each person has an equal probability of being in a treatment or control group. Observational study designs are limited by an inherent imbalance of both known and unknown confounders making some patients more likely to receive surgery than others. As the type of surgery received is not randomly allocated in our study, confounding by indication will be accounted for by using propensity score matching methods. Use of these methods for the assessment of causality in epidemiological studies has been previously described[1]. The propensity score represents the probability that a patient received the intervention (surgery). A logistic equation is fitted where the outcome is actually the main study exposure (i.e. surgical intervention); and an agreed list of covariates (these have already been identified and listed in appendix E) are introduced as potential confounders of the study outcome, namely subsequent re-dislocation. This list has been pre-specified based on clinical knowledge, expert consensus and existing literature. Propensity scores are used then to match each patient receiving surgery to comparable non-surgical controls using a 0·02 standard deviations caliper as demonstrated in previous simulation studies [2]. This is a standard method for minimising confounding by indication, which not only provides participants with balanced baseline characteristics in both surgical and non-surgical groups, but also eliminates surgical patients with no comparable controls [3].
This methodology is now widely used in pharmaco-epidemiology and drug safety, and has both strengths and limitations. The main advantages of PS-matching are:
1. Exclusion of non-comparable subjects (eg non-surgical participants with a very low propensity score who probably have some contraindication or are not fit for surgery, and therefore should not be compared to those who actually underwent surgical repair). 2. This method produces clearly comparable cohorts in terms of observed confounders, and this is highly visual and intuitive.
The main disadvantage (when compared to RCTs) is the lack of adjustment/matching for unobserved confounders. To measure the impact of such unobserved confounding we will use the Rosenbaum boundaries simulation, where one tests the robustness of the estimated effect by introducing a fake confounder. This simulation exercise measures the strength of association between such confounder and the study exposure and outcome that would account for the observed relationship, therefore giving an estimate of the existing risk of residual confounding explaining the findings.

N. Plan for addressing missing data

The handling of missing data is a key issue in routinely collected data analyses. Although no missing is expected for the study exposure or outcomes, it is indeed likely that data will be missing for some of the confounders in our study.

We will impute missing covariates using multiple imputation by chained equations (MICE) methods. We will use the ICE procedure (Imputation by Chained Equations) in Stata, including all predictor variables in the multiple imputation process, together with the outcome variable and length of follow up time on the log scale as this carries information about missing values of the predictors.

O. Limitations of the study design, data sources and analytical methods

The limitations have all been considered and addressed in the other sections. The study has also been designed deliberately in two stages to ensure data validation is undertaken in stage 1 and that the research questions can be answered before progressing to the full observational study.

P. Patient or user group involvement (if applicable)

While there are no patient societies for this common condition, the lead applicant has been running a JLA Priority Setting Partnership (PSP) for *'Surgery for Common Shoulder Problems'* and shoulder instability is an important problem from the patients perspective. Our PSP steering group patient representative who suffered with shoulder instability talked about the impact it has in relation to sports and work, being a more prevalent condition in younger patients with busy lifestyles. This steering group patient felt the problem was poorly understood by many doctors and wanted any 'unknowns' about shoulder instability or best treatments to be researched and results disseminated widely via social media.
This PSP has also allowed the lead applicant to raise the profile of PPI with British surgeons and physiotherapists through BESS with a presentation at the 2014 annual congress. As such many surgeons and therapists have now engaged their patients in completing a national survey for this PSP with many returned surveys asking questions about shoulder instability.
We have identified through our local hospital patient network another patient who is involved and supportive of this research study. We have also contacted our Research Design Services in relation to PPI and have received helpful and useful guidance and advice from the Patient and Public Involvement Officer.
Our patient representative has reviewed and contributed to the plain language summary in this application and will assist the study investigators in identifying relevant study outcomes from a patient perspective. They have also agreed to join the Project Management Board (PMG) if this application is awarded.
Nationally we will use our growing list of JLA PSP partners as an opportunity for further widespread dissemination. The lead applicant is also CI on an ARUK grant studying unmet patient information needs before, during and after surgery, collaborating with patients, primary care and the website 'Health Talk Online' to test and assess technology enhanced patient information (TEPI). Patients in this study have requested more of this type of patient information and so it is likely that the outcomes of our application will inform a shoulder instability module developed with patients and made nationally available via the web.

Q. Plans for disseminating and communicating study results, including the presence or absence of any restrictions on the extent and timing of publication

A detailed manuscript and report will be provided to NIHR HTA for publication in the NIHR HTA Journal. We also plan to publish our research findings in high profile peer reviewed journals. Where possible, we will publish our findings in open access journals, and we have requested some funding to cover these related fees.

The study applicants between them have many national roles and collaborations providing excellent access and influence to disseminate the study findings nationally and internationally through the following societies and funded research centres:

1. *British Elbow and Shoulder Society (BESS)* – Dissemination to all British shoulder surgeons and shoulder physiotherapists. Presentation at the National Congress. (AJC is ex President, AR is Secretary, JLR is Chair of the Research Committee and provides an annual congress report)
2. *British Orthopaedic Society* – AR is chair of the BOA Research Committee and will be able to disseminate results to all orthopaedic surgeons in the UK
3. *NIHR Oxford Biomedical Research Unit/Centre* – Dissemination to all linked patient and local GP networks (AJC is the Director of the BRU)
4. *ARUK Centre of Excellence (CoE) for Sports and Exercise Medicine* – Dissemination to all patients and professional sporting bodies linked to this CoE. (NKA is the Director).
5. *Internationally* we will disseminate through peer review publications and via presentations at the European Shoulder and Elbow Society (SECEC) – (AJC, AR and JLR are all members).

JLR, AJC and AR have all influenced and written national guidelines for NICE and the specialist societies on managing many shoulder conditions including authoring national commissioning guidelines (JLR and AJC). Guidelines for managing traumatic anterior shoulder instability are about to be published as consensus guidelines. This study will allow evidence-based updating of these new guidelines and JLR and AR will be able to influence this as Council members of BESS.
JLR is also the PI on an ARUK grant studying unmet patient information needs before, during and after surgery. His collaboration with primary care to test and assess technology enhanced patient information (TEPI) offers potential for the outcomes of this project to inform a shoulder dislocation and instability TEPI module for national web based dissemination and high impact.

Protocol Amendment.

CPRD have just announced changes to their services for 2016, which includes the cessation of provision of discharge summaries and hospital letters from April 2016. This is a risk to the internal validation section of Work Package 1 of our study as it stands. Therefore to minimise this risk and ensure cost neutrality to our funders (NIHR HTA) we propose a small change to Work Package 1. Rather than obtain 100 sets of notes and use the validation algorithm in Appendix H, we now plan to use the GP's themselves to help validate the data using a GP Questionnaire (Attached in Appendix I). This questionnaire follows the validation algorithm in Appendix H and has some extra questions to ensure maximum data and information is obtained for subsequent analysis. CPRD quote a high 80% return rate with such questionnaires.

This is the only change we are proposing as a consequence of changes to the provision of CPRD services which could not have been expected when the grant application and protocol were written.

R. References

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This project was funded by the National Institute for Health Research Health Technology Assessment (project number 14/160/01).

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Appendix A

TABLE OF CPRD SHOULDER SURGERY CODES

Description	**READ Code**
Shoulder joint operations	**7K4..00**
[SO]Shoulder joint	**7NAD300**
Putti Platt stabilization shoulder	**7K6S700**
Shoulder joint operations NOS	**7K4z.00**
Stabilising operations on joint	**7K6S.00**
Stabilising operation on joint NOS	**7K6Sz00**
Stabilising repair joint capsule	**7K6S000**
[SO]Capsule of joint	**7NAK200**
Other specified stabilising operation on joint	**7K6Sy00**
Open repair of glenoid labrum	**7K6S500**
Stabilising repair of other joint structure	**7K6S600**
Arthroscopic reattachment glenoid labrum	**7K6WR00**
Blocking operation on joint using bone for stabilisation	**7K6S300**
Other stabilising operations on joint	**7K6v.00**
Repair of capsule of joint for stabilisation of joint NEC	**7K6S900**
Open reattachment glenoid labrum	**7K6L800**
Other stabilising operations on joint NOS	**7K6vz00**
[SO]Glenoid labrum	**7NC3500**
Extra-articular ligament reconstruct for stabilisation of joint	**7K6v000**
Repair caps and anter labrum for stabilis glenohumeral joint	**7K6v200**

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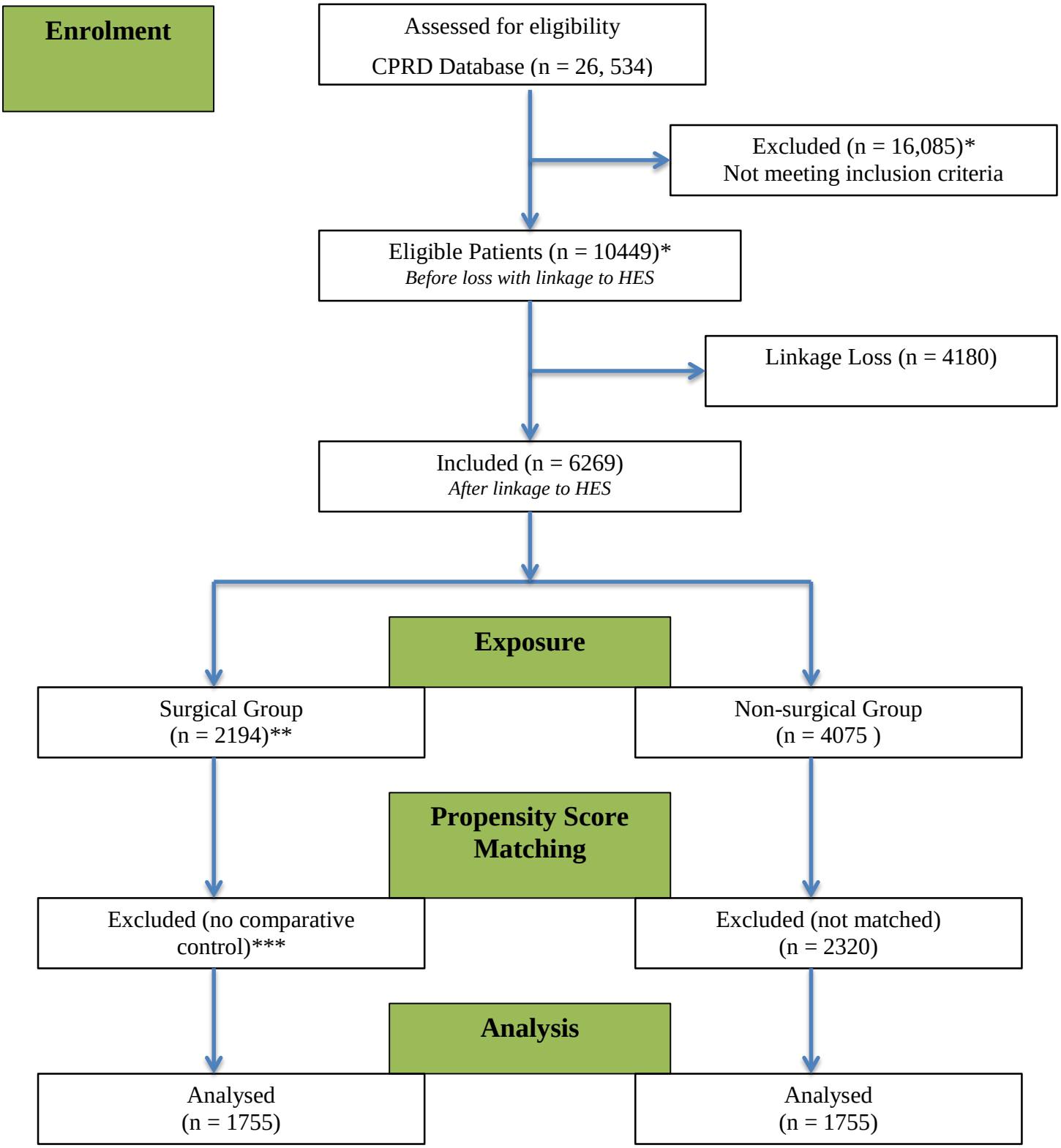
Appendix B
MODIFIED CONSORT 2010
Flow Diagram [WP 2]



* We have estimated similar demographics to data from another country. (Leroux et al., *Epidemiology of primary anterior shoulder dislocation requiring closed reduction in Ontario, Canada.* Am J Sports Med, 2014. **42**)

** We have conservatively estimated 35% of this patient demographic receive the intervention after one dislocation (Malhotra et al., *Management of traumatic anterior shoulder dislocation in the 17- to 25-year age group: a dramatic revelation of practice.* J Shoulder Elbow Surg, 2012. **21**(4): p. 545-55).

*** We have estimated 20% loss during propensity score matching as with similar musculoskeletal epidemiology studies (Kendal et al., *Mortality rates at 10 years after metal-on-metal hip resurfacing compared with total hip replacement in England: retrospective cohort analysis of hospital episode statistics*. BMJ. 2013 Nov 27; 347)

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Appendix C

The HES OPCS 4.7 codes that will be used are shown below. These codes have been provided to the lead applicant by the Expert Advisor in Orthopaedics to the Clinical Classifications Service HSCIC (Health and Social Care Information Centre) and Designated Centre for WHO FIC (Family of International Classifications Network). The codes are based on the following procedures "labral repair, stabilisation, capsular shift, Laterjet, bone transfer, SLAP repair and Bankart repair". For any codes that do not define anatomical site, the following site codes should be present Z81.3 (Glenohumeral Joint) or Z81.4 (Shoulder Joint). The codes in *italics* are usually used for other joints such as the acromio-clavicular joint but we have been informed they are often used for shoulder stablisation of the glenohumeral joint and will therefore need to be included in the analysis during linkage to CPRD shoulder dislocation codes.

HES OPCS 4.7 CODES.

Operative Description	**OPCS 4.7 Codes**
Stabilising operations on joint	**W77**
Repair of capsule of joint for stabilisation of joint NEC	**W77.1**
Transposition of muscle for stabilisation of joint	**W77.2**
Blocking operations on joint using prosthesis for stabilisation of joint	**W77.3**
Blocking operations on joint using bone for stabilisation of joint	**W77.4**
Periarticular osteotomy for stabilisation of joint	**W77.5**
Transposition of ligament for stabilisation of joint	**W77.7**
Other specified stabilising operations on joint	**W77.8**
Unspecified stabilising operations on joint	**W77.9**
Prosthetic replacement of ligament	**W72**
Primary prosthetic replacement of multiple ligaments	**W72.1**
Prosthetic replacement of multiple ligaments NEC	**W72.2**
Primary prosthetic replacement of intra-articular ligament	**W72.3**
Prosthetic replacement of intra-articular ligament NEC	**W72.4**
Primary prosthetic replacement of extra-articular ligament	**W72.5**
Prosthetic replacement of extra-articular ligament NEC	**W72.6**
Other specified prosthetic replacement of ligament	**W72.8**
Unspecified prosthetic replacement of ligament	**W72.9**
Other stabilising operations on joint	**O27**
Extra-articular ligament reconstruction for stabilisation of joint	**O27.1**

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Repair of capsule and anterior and posterior labrum for stabilisation of glenohumeral joint	**O27.2**
Repair of capsule and anterior labrum for stabilisation of glenohumeral joint	**O27.3**
Repair of capsule and posterior labrum for stabilisation of glenohumeral joint	**O27.4**
Other reconstruction of ligament	**W74**
Reconstruction of multiple ligaments NEC	**W74.1**
Reconstruction of intra-articular ligament NEC	**W74.2**
Other specified other reconstruction of ligament	**W74.8**
Unspecified other reconstruction of ligament	**W74.9**
Other open repair of ligament	**W75**
Open repair of multiple ligaments NEC	**W75.1**
Open repair of intra-articular ligament NEC	**W75.2**
Open repair of extra-articular ligament NEC	**W75.3**
Other specified other open repair of ligament	**W75.8**
Unspecified other open repair of ligament	**W75.9**
Therapeutic endoscopic operations on other joint structure	**W84**
Endoscopic repair of intra-articular ligament	**W84.1**
Endoscopic reattachment of intra-articular ligament	**W84.2**
Endoscopic repair of superior labrum anterior to posterior tear	**W84.7**
Other specified therapeutic endoscopic operations on other joint structure	**W84.8**
Unspecified therapeutic endoscopic operations on other joint structure	**W84.9**
Capsulorrhaphy of joint	**W81.6**

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APPENDIX D

TABLE OF CPRD DISLOCATION READ CODES

Description	READ Code	Number of clinical events currently recorded in CPRD
Dislocation or subluxation of shoulder	**S41.00**	51,162
Dislocation of shoulder NOS	**S41z.00**	11,578
H/O: dislocated shoulder	**14G5.00**	6,724
Closed reduction of dislocation of shoulder	**7K6G300**	2,878
Closed traumatic dislocation of shoulder	**S410.00**	2,240
Recurrent dislocation of shoulder – anterior	**N083A00**	2,140
Anterior dislocation of shoulder	**S410111**	1,864
Recurrent joint dislocation, of shoulder region	**N083100**	1,321
Recurrent subluxation of shoulder – anterior	**N083C00**	599
Closed traumatic dislocation shoulder jnt. Anterior (sub-coracoid)	**S410100**	439
Closed traumatic dislocation shoulder joint, unspecified	**S410000**	439
Closed traumatic subluxation, shoulder	**S412.00**	288

APPENDIX E

Table of Expert Consensus List of Risk Factors.

Risk factors for re-dislocation after first dislocation	Risk factors for re- dislocation after surgery
Age	Age
Gender	Gender
UK Region	UK Region
Deprivation Scores	Deprivation Scores
Glenoid and / or Humeral Bone loss	Glenoid and / or Humeral Bone loss
Mechanism of injury	Number of dislocations pre-surgical repair
Rotator cuff tears	Time between first dislocation and surgery
Imaging findings	Anterior apprehension
Anterior apprehension	Occupation
Occupation	Sport type and level
Sport type and level	Operation type
Neurological injury	Laxity/Beighton Score
Laxity/Beighton Score	Insufficient physio / rehab after surgery
Insufficient physio / rehab after first dislocation	Time for return to sports
Young Rugby player under 20	Number of anchors used at surgery
Time at return to sports	Incorrect positioning of anchors
Post dislocation immobilisation	Not addressing capsular laxity at surgery
	Previous lower limb or back injury

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APPENDIX F

METHOD FOR LINKAGE OF CPRD AND HES DATASETS

CPRD data is linked to HES using the HESID identifier. Over 60% of the CPRD population is currently linked to HES. The linkage of CPRD to HES data is a 2-step process: (1) The creation of a unique and anonymous ID in HES for each patient (HESID), and (2) Linkage of CPRD to HES using the HESID index. The detailed protocol on creating a HESID is publicly available online (http://www.hscic.gov.uk/media/1370/HES-Hospital-Episode-Statistics-Replacement-of- the-HES-patient-ID/pdf/HESID_Methodology.pdf).
In summary the majority of hospital admission episodes are linked using a combination of sex + date of birth (dob) + NHS number (step 1) OR sex + dob + [postcode + local hospital generated patient identifier] (step 2). Since 2009 a third step was added to try and increase the linkage in early years where NHS number was less completely recorded. This allows for a match on sex + dob + postcode, but only where this does not lead to a HESID being associated with 2 different NHS numbers, and only where the postcode is not on the list of known communal establishments (nursing homes, army barracks, prisons). In the past 10 years, NHS number has been complete for >95% of all records so the HESID should be particularly reliable during this period. Efficiency of the HESID algorithm may have been lower in earlier years when the completeness of recording of NHS number was lower.
Linkage CPRD-HES using the HESID: HES use a standard 8 pass algorithm to link HES to CPRD data via the HESID index (Detailed information is available online at http://www.hscic.gov.uk/media/11668/HES-ONS-Mortality-Data-Guide/pdf/guide_to_linked_ONS_HES_mortality_data_V4_040613.pdf.
The 8 passes involved are:

Pass 1 - Exact NHS, sex, DoB, Postcode
Pass 2 - Exact NHS, sex, DoB,
Pass 3 - Exact NHS, SEX, postcode, partial DOB
Pass 4 - Exact NHS, SEX, partial DOB
Pass 5 - Exact NHS, postcode
Pass 6 - Exact sex, dob and postcode (where NHS doesn't contradict the match, DOB not 1st of January & postcode not on the ignore list)
Pass 7 - Exact sex, DOB and postcode (where NHS doesn't contradict the match and dob is not 1st of January)
Pass 8 - Exact NHS

After this whole process, CPRD only keeps matches that are identified in passes 1 through 5. This means that the match must be on NHS number plus at least one other piece of information (and in most cases 2 other pieces).
Given that the NHS number is available for 98-99% of CPRD patients, and for >95% of HES patients, the HES linkage methodology is considered very

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Appendix G

TABLE OF CPRD PHYSIOTHERAPY CODES

Description	**READ Code**
Seen in physiotherapy department	**9N1yE00**
Physiotherapy	**8E…11**
Refer to Physiotherapist	**8H77.00**
Seen in physiotherapy department	**9N0F.00**
Physiotherapy/remedial therapy	**8E…00**
In-house physiotherapy	**9NJ3.00**
Seen by physiotherapist	**9N28.00**
Refer to Physiotherapist	**ZL85.11**
Discharge by Physiotherapist	**ZLDM.00**
Referral to Physiotherapist	**ZL85.00**
In-house physiotherapy follow up appointment	**9NJm.00**
Discharge from physiotherapy service	**ZLEK.00**
Physiotherapy	**Z6…00**
In-house physiotherapy first appointment	**9NJk.00**
Physiotherapy manipulation	**82D4.00**
Physiotherapist	**03J1.00**
Refer to community physiotherapist	**8HHA.00**
In-house physiotherapy discharge	**9NJl.00**
Discharge for hospital physiotherapy service	**ZLEK100**
Other physiotherapy	**8EZ..00**
Refer to domiciliary physiotherapy	**8HH5.00**
Referral to community physiotherapy	**ZL85111**
Discharge by hospital based physiotherapist	**ZLDM200**
Discharge by community based physiotherapist	**ZLDM100**
Private referral to physiotherapist	**8HVb.00**
In house physiotherapy – domiciliary visit	**9NJ4.00**
Discharge from community physiotherapy service	**ZLEK200**
Discharge from community physiotherapist	**ZLDM111**
Under care of physiotherapy	**ZL4A.00**
Referral to community based physiotherapist	**ZL85100**
Discharge by hospital physiotherapist	**ZLDM211**
Under the care of community physiotherapist	**ZL4A111**
Referral to hospital based physiotherapist	**ZL85200**
Under the care of community based physiotherapist	**ZL4A100**
Referral to hospital physiotherapist	**ZL85211**
Referral to orthopaedic physiotherapist practitioner	**8Hl2.00**
Seen by intermediate care physiotherapist	**9Nl9.00**
Referred by physiotherapist	**9N6B.00**
Under the care of hospital physiotherapist	**ZL4A211**
Under the care of hospital based physiotherapist	**ZL4A200**
PT -Physiotherapy	**Z6…11**

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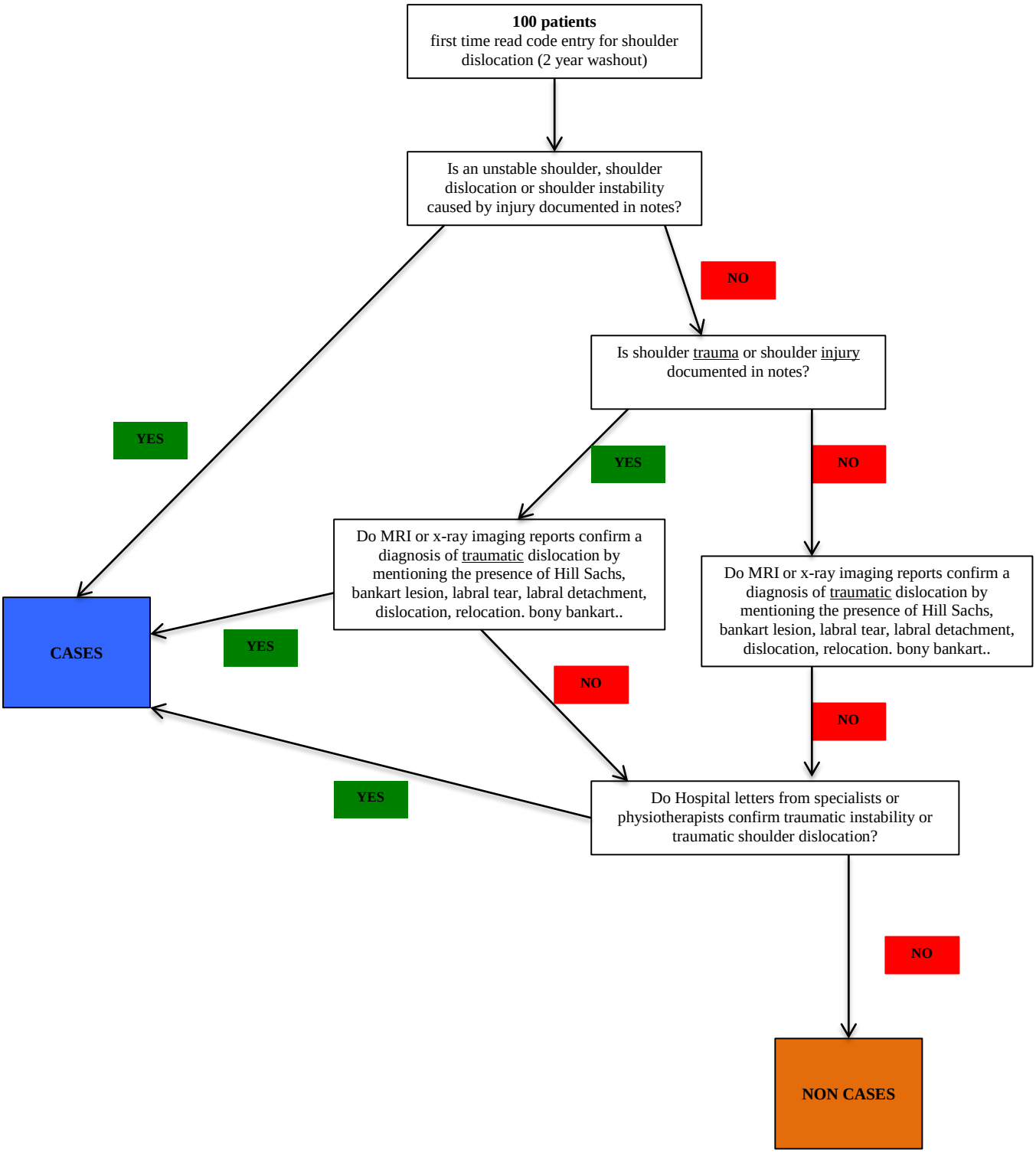
Appendix H

Validation Algorithm



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Appendix I

GP CPRD Validation Questionnaire for the UK.TASH-D Study

Dear Colleague,

Thank you for completing this questionnaire as a practice connected to the CPRD database. The UK.TASH-D study will use the CPRD to investigate the treatment of first time traumatic anterior shoulder dislocation. As you know, shoulder dislocations often recur and we are investigating whether surgery makes recurrence less likely after a first episode. We will be completely reliant in the main phase of this study on electronic codes to identify recurrences.

Before starting the main phase, we need to know whether we can reliably identify 'New dislocation episodes' or whether these tend to be recorded as a 'Review' of the same problem (without a further dislocation occurring). Conversely, we need to know if codes apparently indicating a 'further' dislocation episode are in fact a 'Review' of the problem. We also need to confirm that codes recorded in primary care as 'dislocation' actually reflect this diagnosis, rather than less specific conditions affecting the shoulder.

We are therefore looking at a national sample of records that indicate a shoulder dislocation, and by completing the following questionnaire on your patient, you will help tell us:

1) Was this actually a traumatic shoulder dislocation?

2) Did further episodes occur over the following two years, and if so, how many true recurrences were recorded as 'New' episodes?

3) Were there any examples of 'New' recurrences being recorded as a 'Review' of the original problem?

If the coding proves valid and reliable, then a CPRD dataset will be linked to a Hospital Episode Statistics (HES) dataset to compare surgical versus conservative treatment (including physiotherapy) on recurrent dislocation rates. Our aim is that this will result in national pathway guidelines for the management of this condition in primary care.

Thank you in anticipation of your help

The UK.TASH-D study team.

Number	Question	Response (please tick)	
		Yes	No
1.	Is shoulder dislocation, an unstable shoulder, or shoulder instability caused by INJURY documented in the patient's notes?	*(If YES go to Q5)*	*(If NO go to Q2)*
2.	Is shoulder trauma or shoulder injury documented in the patient's notes?	*(If YES go to Q3)*	*(If NO go to Q3)*
3.	Do MRI or X-ray imaging reports confirm a diagnosis of traumatic dislocation by mentioning the presence of Hill Sachs, Bankart lesion, labral tear, labral detachment, dislocation, relocation, bony Bankart?	*(If YES go to Q5)*	*(If NO go to Q4)*

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4.	Do Hospital letters from specialists or physiotherapists confirm traumatic instability or traumatic shoulder dislocation?	*(If YES go to Q5)*	*(If NO go to Q8)*
5.	Is there any record of a dislocation prior to the CPRD first registration date at your practice?	*(If YES go to Q6)*	*(If NO go to Q6)*
6.	Are there any further dislocation codes in the record during the 2 years after the first dislocation code?	*(If YES go to Q6b)*	*(If NO go to Q6c)*
6b.	If YES is it clear (for each one) that this is a further dislocation episode rather than simply a review of the problem?	*(If YES go to Q7)*	*(If NO go to Q7)*
6c.	If NO, have there been any further dislocations recorded during the following 2 years that are not electronically coded?	*(If YES go to Q7)*	*(If NO go to Q7)*
7.	Are there any physiotherapy treatment codes for 2 years after the first dislocation code?	*(If YES go to Q7b)*	*(If NO go to Q7c)*
7b.	If YES is it clear that this physio code indicates the patient received physiotherapy for their shoulder?	*(If YES go to Q8)*	*(If NO go to Q8)*
7c.	If NO, is there any documentation that the patient has received physiotherapy for their shoulder without a code being entered?	*(If YES go to Q8)*	*(If NO go to Q8)*
8.	If your specific responses to this questionnaire indicate that this patient has not had a traumatic shoulder dislocation but your reading of the notes or your knowledge of the patient suggest they might have please tick the YES box, otherwise tick the NO box.	*The end – thank you*	*The end – thank you*

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