Online appendix 1

Table A. Changes and improvements to the NE descriptions suggested by GPs

Short description	Changes suggested by GPs
Prescribing aspirin for a patient ≤12 years	specify age 16 not 12 to agree with guidelines; exclude topical treatments; replace aspirin with aspirin containing products *e.g.* Bonjela; make it clear that exceptions are permitted but should be documented justification *e.g.* by consultant for inflammatory arthritis *etc.*
Methotrexate prescribed daily rather than weekly	include 'taking' as well as prescribing *eg* due to lack poor explanation to patient; specify prescription is an error or incorrectly prescribed; specify prescribing occurs in general practice
Adrenaline is NOT available when needed	remove home visit as only a NE in surgery; add adrenaline should be within expiry date; clarify how critical the adrenaline is/what the emergency is; define "within minutes" more specifically
Prescribed teratogenic drug when pregnant	add “recorded” as well as “known” to be pregnant; specify the level of teratogenicity and drug class; specify the type of clinical specialist; *e.g.* epilepsy mental health *etc*; note is acceptable if the benefits outweigh the risks; include drugs initiated prior to pregnancy
Prescribed HRT & has intact uterus	add without IUS (*eg* Mirena); add “…in whom there is no regular monitoring for evidence of endometrial hyperplasia”; specify means oral as topical oestrogen may be used with an intact uterus; specify time scale *e.g.* more than 3m continuously or on repeat prescription; clarify timescale from last period and age > 50 as " period free” HRT is licenced; add “…unless under instruction by consultant Gynaecologist/Oncologist”; specify names of HRT products
Cancer referral not sent	timescale is needed (delayed should be considered as well as missed); clarify referrer is in primary care; define level of suspicion *e.g.* to confirm rather than "suspect"; should really apply to any planned referral
Ambulance transport is not arranged	clarify emergency *e.g.* Is it 999 ambulance for an acute emergency?; specify how quick the response should be; add “…agreed as the most appropriate mode of transport” and “results in unnecessary delay or suffering”; specify who made the agreement - the GP/ practice admin staff/ ambulance service?; specify it is transport not arranged rather than transport not occurred; exclude psychiatric emergency admissions as secondary care arranges "appropriate" transport
Needle stick injury due to sharps disposal failure	perhaps "accidental" might be more acceptable than "failure to follow guidelines"; include any needle stick/sharps injury; make clear is only in relation to the disposal of sharps; clarify systems failure vs simple accident (due to overflowing bin vs doing it to yourself)
Prescribing when adverse reaction recorded	clarify severe adverse reaction vs. intolerance *e.g.* caused a severe proven documented adverse reaction which is potentially life threatening or the patient had a serious or anaphylactic reaction; define spectrum of allergy
Abnormal investigation result is not reviewed	provide a timescale; specify clinically significant *e.g.* critically abnormal or life threatening; replace reviewed with actioned; the investigation should have been initiated by the practice (GPs receive unrequested results); remove abnormal because all results should be reviewed by a clinician

Table B1. Number of comments related to each theme for the NE below

Prescribing Aspirin for a patient ≤ 12 years old (unless recommended by a specialist for specific clinical conditions e.g. Kawasaki's disease)		
Topics raised in GP comments	N (%) Total=70	Example comment
NE so rare it is not a useful measure of quality or is a historical problem	17 (24%)	*If you ask older GPs you will find many of us who would have prescribed aspirin to under 12's in the 1980's.* *I imagine this is something that is incredibly rare as current education of undergraduates hammers this information…*
Suggested changes or clarification	13 (19%)	Guidelines specify age 16 not 12 Exclude topical treatments Replace aspirin with aspirin containing products *e.g.* Bonjela …to a child under 12 without documented justification …unless indicated by consultant for inflammatory arthritis etc
Computer systems are helpful to prevent NE	12 (17%)	*Prescribing software (Vision) makes accidental prescribing in this case much less likely as flags up warning*
Risk of harm to patient due to NE is very small	9 (13%)	*Reyes syndrome - the most serious negative consequence of this event is extremely rare, so prescription is highly unlikely to result in harm*
NE can occur for clinical reasons	5 (7%)	*Have one child on Aspirin for subclavian artery obstruction and stroke*
Specific to an individual *e.g.* trainee or problem individual	5 (7%)	*I would like to think this could never happen. But worry an inexperienced/ remedial GP trainee could potentially make this error.*
Other	9 (13%)	

Table B2. Number of comments related to each theme for the NE below

Prescribing Methotrexate daily rather than weekly (unless initiated by a specialist for a specific clinical condition e.g. leukaemia)		
Topics raised in GP comments	N (%) Total=93	Example comment
Computer systems are helpful to prevent NE	45 (48%)	*Our EMIS Web system is configured so it will not let you prescribe it daily - even if you really tried!*
Description of prevention strategies or sharing reasons behind the NE	14 (15%)	*After an SEA on a MTX case we have very strict protocols about ensuring the patient completely understands how to take their MTX and folic acid properly and that they are aware of the risks and reasons for the blood tests*
Suggested changes or clarification	7 (8%)	Include 'taking' as well as prescribing *eg* due to lack poor explanation to patient Prescribed as a daily dose in error, rather than the recommended single weekly dose Prescribing methotrexate incorrectly as a dosage size or frequency Specify prescribing is in general practice
Pharmacists can play a role in preventing the NE	6 (6%)	*I think this has happened in our practice once but the chemist spotted it before dispensing*
Computer systems are unhelpful or increase risk of NE	6 (6%)	*minor errors when generating repeat prescriptions in the past when ….prescribing system defaults to a previously issues quantity /dose*
NE can occur due to error outside of general practice *e.g.* ambulance, laboratory	5 (5%)	*…the patient was not given daily treatment but the hospital letter erroneously stated "daily"…*
Other	10 (9%)	

Table B3. Number of comments related to each theme for the NE below

Adrenaline/Epinephrine is NOT available within minutes when clinically indicated for a medical emergency in the practice or GP home visit		
Topics raised in GP comments	N (%) Total=188	Example comment
Home visits increase the risk of the NE happening	60 (32%)	*I and many of my GP colleagues do not take adrenaline on routine home visits.*
Description of prevention strategies or sharing reasons behind the NE	37 (20%)	*All GPs carry adrenaline in their bag, nurse has register of expiry dates and updates as needed, also have emergency drugs trolley with adrenaline in clinicians room.*
NE so rare it is not a useful measure of quality or is a historical problem	25 (13%)	*Never used adrenaline in 30 yrs clinical practice*
Medicine out of date more likely than not available	23 (12%)	*often the potential danger is that the ampule can be out of date when required*
Suggested changes or clarification	20 (11%)	Only a NE in surgery, remove home visit Add adrenaline should be within expiry date Clarify how critical the adrenaline is/what the emergency is Define "within minutes"
There may be a better option to deal with the situation *e.g.* call ambulance	14 (7%)	*It depends on ambulance availability in your town. I have worked in areas where ambulances were miles away, but here they can be outside within one min*
Other	9 (5%)	*I had left my drugs bag locked in the practice to allow the controlled drug inspector to see the opiates while I was on leave and the key was with another individual when I needed to go on housecall.*

Table B4. Number of comments related to each theme for the NE below

Prescribing a teratogenic drug to a patient the clinician knows to be pregnant (unless advised to do so by a clinical specialist)		
Topics raised in GP comments	N (%) Total=50	Example comment
NE description needs to be more specific *e.g.* the level of the teratogenicity or severity of ADR	14 (28%)	*problem is that lots of drugs have small risk of teratogenicity eg SSRIS - difficult to know where to draw the line, some drugs with low risk may be prescribed by GPs (eg SSRIs) others continued while awaiting specialist confirmation eg anti-epileptics*
NE can occur for clinical reasons	12 (24%)	*Sometimes we prescribe antidepressants in pregnancy where the benefit may be great*
Patients can be helpful in preventing NE	9 (18%)	*…depends on how certain it is the clinician knew pt pregnant. Whether they should have known is another matter*
Suggested changes or clarification	9 (18%)	Known to be, or recorded as, pregnant Define teratogenicity and drug class Clarify type of clinical specialist..eg this stuff crops up in epilepsy mental health etc …or the benefits are significantly outweighed by the risks Include drugs initiated prior to pregnancy
Description of prevention strategies or sharing reasons behind the NE	2 (4%)	*We do check the MIMS before prescribing any drugs to pregnant ladies*
Other	4 (8%)	*…two were due to failure of the initiating clinician (not GPs at my practice) to inform the woman of child-bearing age that the drug was teratogenic.*

Table B5. Number of comments related to each theme for the NE below

Prescribing systemic oestrogen-only Hormone Replacement Therapy for a patient with an intact uterus		
Topics raised in GP comments	N (%) Total=93	Example comment
Description of prevention strategies or sharing reasons behind the NE	15 (16%)	*There is often mix up between Climaval (oestrogen only HRT) and Climagest (sequential HRT)*
Suggested changes or clarification	15 (16%)	…without IUS (*eg* Mirena) should be added. …in whom there is no regular monitoring for evidence of endometrial hyperplasia Specify means oral forms of oestrogen - topical forms may be used with an intact uterus Specify time scale eg more than 3m continuously or on repeat prescription Clarify timescale from last period and age > 50 as " period free" HRT is licenced …unless under instruction by consultant Gynaecologist/Oncologist Specify names of HRT products
NE can occur for clinical reasons	12 (13%)	*As far as I am aware only problem with long-term use - initial therapeutic loads not problematic or for HRT while awaiting hysterectomy*
Human error is inevitable or NE is difficult to prevent	10 (11%)	*Always possible to tick on the wrong drop down box when prescribing or get your HRT preparations mixed up*
Specific to an individual *e.g.* trainee or problem individual	10 (11%)	*The three patients were all seen by one clinician. This has been dealt with as a significant event.*
Computer systems are helpful to prevent NE	8 (9%)	*Initiating doctor asked to enter code HRT commenced and stopped. This includes rider if combined or not and whether patient has had a hysterectomy. Hopefully this lessens risk*
NE can occur due to error outside of general practice *e.g.* ambulance, laboratory	5 (5%)	*Became aware of patient who transferred from another practice with this issue, which raised the alert on how to identify/prevent such events in future.*
NE so rare it is not a useful measure of quality or is a historical problem	5 (5%)	*This is so well known now unlikely ever to happen but did happen 20 years ago* *there is only a theoretical increased risk of endometrial cancer in this scenario*
Patients can increase the risk of a NE	4 (4%)	*I have been informed by migrant/foreign patients before that hysterectomy has taken place abroad when this is not actual fact.*
Computer systems are unhelpful or increase risk of NE	3 (3%)	*GP systems for coding may lead a clinician to believe a woman has had a hysterectomy when in fact she had a "subtotal hysterectomy". GPs may be caught out by this.*
Incorrect or incomplete records can contribute to NE	3 (3%)	*Hysterectomy can sometimes not be recorded in patients GP notes then can cause this never event*

Pharmacists can play a role in preventing the NE	1 (1%)	*… a role for pharmacies checking as a further safety-net*
Evidence of harm due to NE is not clear cut	1 (1%)	*…some research indicates that the increased risk of breast cancer from progesterone is greater than the decreased risk of endometrial cancer. The correct treatment may be to reduce the frequency of progesterone (and always avoid combined treatment)*
The NE has serious consequences	1 (1%)	*it would be indefensible in court if patient went on to have endometrial ca. after this*

Table B6. Number of comments related to each theme for the NE below

A planned referral of a patient, prompted by clinical suspicion of cancer, is not sent		
Topics raised in GP comments	N (%) Total=125	Example comment
Human error is inevitable or NE is difficult to prevent	29 (23%)	*We class this as an actual "SEA". However, it is usually human error/forgetting to do referral which has been to blame and no amount of "system fail safe" can eliminate this.*
Description of prevention strategies or sharing reasons behind the NE	21 (17%)	*I keep a list of suspected cancer referrals and check that it has been faxed or not. (Fail safe method which works for me!). This might look overbearing but it is not.*
Computer systems are unhelpful or increase risk of NE	13 (10%)	*Relatively easy to send something electronically but not to complete the process and find it is still parked*
Delay is more likely than referral not sent or result not reviewed	13 (10%)	*The problem is not that referrals are not sent but that the referral is delayed by a few days*
Suggested changes or clarification	9 (7%)	Timescale is needed (delayed should be considered as well as missed) Clarify referrer - primary care or secondary care? 1. RBMS vs. practice vs. consultant Define level of suspicion eg to confirm rather than "suspect" Should really apply to any planned referral
Patients can be helpful in preventing NE	9 (7%)	*We routinely hand the patient an information leaflet that prompts them to take action if appointment is not received.*
NE occurs due to large volume of results or referrals, insufficient time & work load, GP absence	7 (6%)	*happens when a GP has a very long stressful surgery running on to some other highly pressurised task. I think most GPs would admit to waking up overnight remembering that they forgot to do a referral letter that day - and sort it the next day.*
NE can occur due to error outside of general practice *e.g.* ambulance, laboratory	6 (5%)	*faxed to hospital - but they had changed the fax number but not informed general practice*
Computer systems are helpful to prevent NE	5 (4%)	*Choose and book system is robust especially if appointment is booked while patient still present.*
Administrative errors can play a major role including poor communication	5 (4%)	*Referral missed by secretary but patient rang 5 days later and referred urgently 2WW*
Specific to an individual *e.g.* trainee or problem individual	3 (2%)	*We have one partner who misses referrals, we have approached the individual about this. Generally they are inclined to be less vital referrals but a scope was not ordered…*
Patients can increase the risk of a NE	2 (2%)	*Have a patient who has failed to complete referral though on both occasions these were picked up quickly.*
Other	3 (2%)	

Table B7. Number of comments related to each theme for the NE below

Ambulance transport is not arranged if this had been agreed when deciding to admit a patient as an emergency		
Topics raised in GP comments	N Total=136	Example comment
NE can occur due to error outside of general practice *e.g.* ambulance, laboratory	28 (21%)	*Even though ambulance was arranged by the practice for an emergency it did not turn up following a home visit in the last year*
Suggested changes or clarification	25 (18%)	Need to clarify emergency - not all emergency admissions are urgent and life threatening eg Is it 999 ambulance for an acute emergency or is it for other less acute situations Need to specify how quick the response should be …agreed as the most appropriate mode of transport …and results in unnecessary delay or suffering Agreed by whom? The GP seeing the patient? His practice admin staff? The ambulance service? Is it transport not arranged or did transport not occur? where is the "failure"? exclude psychiatric emergency admissions as secondary care arranges "appropriate" transport
Description of prevention strategies or sharing reasons behind the NE	23 (17%)	*GPs tend to arrange ambulance transport themselves. I don't allow staff to arrange ambulance transport for patients, I have seen and need to admit.*
Human error is inevitable or NE is difficult to prevent	22 (16%)	*The sort of thing that happens when everyone is stretched and busy*
Administrative errors can play a major role including poor communication	12 (9%)	*Relies on message given to receptionist to act accordingly. Human error can creep in*
Patients can be helpful in preventing NE	9 (7%)	*…the only failsafe to the clinician forgetting is the patient or carer being asked to re-contact*
Patients can increase the risk of a NE	7 (5%)	*some patients insist on having others take them other than ambulance, even though this is against medical advice*
Other	10 (7%)	*This was done by a stressed trainee. A member of staff actually offered to do this task and trainee insisted they would do. I think an SEA after something like this is useful- a possible indicator of underperformance due to stress*

Table B8. Number of comments related to each theme for the NE below

A needle-stick injury due to a failure to dispose of 'sharps' in compliance with national guidance and regulations		
Topics raised in GP comments	N (%) Total=95	Example comment
Human error is inevitable or NE is difficult to prevent	29 (31%)	*something which involves people handling a sharp object thousands of times a year can result in an accident.*
Suggested changes or clarification	21 (22%)	"A person should never be subject to a needle stick from a discarded needle" "failure to follow guidelines" suggests "failure" and people are less likely to admit to "failure" leading to under reporting?? perhaps "accidental" might be more acceptable Any needle stick/sharps injury, not just due to failure to dispose of sharps... Make clear is only in relation to the disposal of sharps Clarity about systems failure vs simple accident (ie needlestick due to overflowing bin vs doing it to yourself) This is a serious staff safety event not patient safety event
Home visits increase the risk of the NE happening	13 (18%)	*GPs particularly poor at this - I forget to take a small sharps bin out with me on visits so re-sheathing needles to dispose of back at the practice a risky time*
Description of prevention strategies or sharing reasons behind the NE	12 (13%)	*increasingly unlikely to happen with the use of new needles and systems/ kits being made available to the community. Mind you, this seems to vary i.e. a neighbouring CCG has decided not to implement the recommendations*
Specific to an individual *e.g.* trainee or problem individual	8 (8%)	*I suffered a needle stick injury from a used needle left on my desk under papers by a colleague using my room -- within the last five years*
Danger is more to another individual than patient *e.g.* cleaner	7 (7%)	*Has happened to a cleaner here recently - sharp bin too full*
Other	5 (5%)	*Risk of transmission of infection in most cases v. small. All staff vaccinated against Hep B. All clinical staff aware of patients with increased risk.*

Table B9. Number of comments related to each theme for the NE below

Prescribing a drug to a patient that has correctly been recorded in the practice system as having previously caused her/him a severe adverse reaction		
Topics raised in GP comments	N (%) Total=197	Example comment
NE can occur due to incorrect or poor record keeping	30 (19%)	*Information recorded not always accurate. Patient has severe allergic reaction recorded but since taken this many times therefore continue to prescribe.*
Computer systems are unhelpful or increase risk of NE	29 (15%)	*So many drug warnings thrown up by the computer that there is alert fatigue - and they are all ignored.*
Home visits increase the risk of the NE happening	29 (15%)	*the risk is much greater on housecalls (especially with dementia patients who cannot easily warn you themselves) when prescriptions are being handwritten without the benefit of computer warnings*
NE can occur for clinical reasons	29 (15%)	*Retrial of drugs is commonly done... eg perhaps initial Risk was low or equivocal ...or perhaps the new indication trumps the risk... too many variables*
Computer systems are helpful to prevent NE	23 (12%)	*The computer prescribing systems are better now at prompting you regarding allergies.*
Suggested changes or clarification	18 (9%)	Clarify severe adverse reaction vs. intolerance caused a severe proven documented adverse reaction which is potentially life threatening …the patient had a serious or anaphylactic reaction Define spectrum of allergy
Human error is inevitable or NE is difficult to prevent	9 (5%)	*This is too frequent. Medication errors are very common*
Description of prevention strategies or sharing reasons behind the NE	6 (3%)	*Errors in Px information for elderly patient despite warning. But Dr had noted this had already been issued 2x after date of having with no repeated S/E. Patient admitted to hospital fallowing significant event and reported to local health authority*
Patients can be helpful in preventing NE	3 (2%)	*Fortunately the patients generally recognised the error before any adverse outcome*
Particular individuals may be more prone to the NE *e.g.* trainees, stressed or poor clinicians	3 (2%)	*again it depends on practitioners following protocols...when it happened to us an FY2 deliberately over rode the warnings on the computer on several levels...how do we stop that?*
Patients can increase the risk of a NE	2 (1%)	*With patients' increased demands and multiple routes, 24 hours a day to access health care, chances of receiving medication is higher, and therefore more chance of being prescribed something by someone not familiar with the patient is higher. Also often patients don't remember what they might be allergic too.*
NE can occur due to error outside of general practice *e.g.* ambulance, laboratory	2 (1%)	*Problems with communication between primary and secondary care leads to more potential for this to happen*
Pharmacists can play a role in preventing the NE	2 (1%)	*On the occasion when it did happen, pharmacist picked it up.*
Other	12 (6%)	

Table B10. Number of comments related to each theme for the NE below

An abnormal investigation result is received by a practice but is not reviewed by a clinician		
Topics raised in GP comments	N (%) Total=299	Example comment
Suggested changes or clarification	49 (16%)	Needs a timescale Specify clinically significant, critically abnormal or life threatening Replace reviewed with actioned Investigation should have been initiated by the practice Remove abnormal, all results should be reviewed by a clinician
More likely that abnormal result missed or inappropriate action taken	34 (11%)	*There have been times when a clinician has not adequately reviewed results or adequately acted on abnormal results before filing them. This is usually due to doctor error.*
Not all abnormal results are clinically significant	25 (8%)	*It depends what you mean by abnormal results. Lots of results are abnormal, only a few are associated with life threatening or serious consequences.*
Computer systems are helpful to prevent NE	22 (7%)	*All results come in to the practice electronically and have to be reviewed and filed by a clinician. They stay in workflow until they are filed by the clinician.*
Delay is more likely than referral not sent or result not reviewed	22 (7%)	*Often delayed reporting (1-2 weeks later patient seen by GP, but blood results in a colleagues repeat box but no action)*
NE description needs to be more specific *e.g.* the level of the teratogenicity or severity of ADR	21 (7%)	*Abnormal investigation is an ambiguous term. As could be improvement from previous result or could be out of normal limits but still considered acceptable in clinical practice. E.g. Vit D, Vit B12*
Description of prevention strategies or sharing reasons behind the NE	20 (7%)	*Recent issue with lab not returning report as district nurse bloods did not have 'location' as their label trace only displayed dr and practice code - lab said this was not enough info to return result. SEA has been undertaken and lab and DN practice changed.*
Administrative errors can play a major role including poor communication	17 (6%)	*Once happened to a colleague due to receptionist filing an abnormal (paper) result without it having been seen by a doctor.*
NE occurs due to large volume of results or referrals, insufficient time & work load, GP absence	26 (9%)	*Results sometimes sent to GPs on annual leave and therefore not actioned until returned.* *Clinicians or often flooded with results that they didn't order. These will be reviewed but not necessarily noticed or acted upon. It's one of these high risk areas …*
Unclear who is responsible for checking the result	17 (6%)	*The responsibility must lie with the requesting clinician*
Computer systems are unhelpful or increase risk of NE	13 (4%)	*This has only occurred due to a computer software problem*
Human error is inevitable or NE is difficult to prevent	12 (4%)	*Give us more time with results/pts - the best way to improve safety!*
By definition the GP may be unaware of the NE	9 (3%)	*"things can't be found without being seen..."* *"if not seen and no adverse affects, might never come to*

		light"
NE can occur due to error outside of general practice *e.g.* ambulance, laboratory	7 (2%)	*we carried out an SEA, main issue was related to the format the results now arrive in practice, no GP input into this and labs refuse to even consider a change*
Patients can be helpful in preventing NE	3 (1%)	*We ask patients to contact practice for results to act as a safety net.*
Patients can increase the risk of a NE	2 (1%)	*Patient 'does not' respond to recall*

Table C. GP estimates that Never Event will occur in next 5 years (Q4, Box 2 in main paper)

Never Event	No chance	Very unlikely	Unlikely	Moderate chance	Likely	Very Likely	Certain to happen	Missing
Prescribing aspirin for a patient ≤12 years	155 (28%)	349 (63%)	32 (6%)	5 (1%)	4 (1%)	0	0	11 (2%)
Methotrexate prescribed daily rather than weekly	134 (24%)	366 (66%)	35 (6%)	9 (2%)	4 (1%)	2 (<1%)	1(<1%)	5 (1%)
Adrenaline is NOT available when needed	120 (22%)	302 (54%)	74 (13%)	40 (7%)	4 (1%)	6 (1%)	3 (1%)	7 (1%)
Prescribed teratogenic drug when pregnant	51 (9%)	335 (60%)	112 (20%)	34 (6%)	8 (1%)	3 (1%)	2 (<1%)	11 (2%)
Prescribed HRT & has intact uterus	34 (6%)	315 (57%)	140 (25%)	46 (8%)	13 (2%)	1 (<1%)	2 (<1%)	5 (1%)
Cancer referral not sent	26 (5%)	326 (59%)	116 (21%)	59 (11%)	17 (3%)	4 (1%)	2 (<1%)	6 (1%)
Ambulance transport is not arranged	83 (15%)	304 (55%)	94 (17%)	45 (8%)	18 (3%)	3 (1%)	0 (<1%)	9(1%)
Needle stick injury due to sharps disposal failure	30 (5%)	252 (45%)	151 (27%)	99 (18%)	15 (3%)	3 (1%)	3 (1%)	3 (1%)
Prescribing when adverse reaction recorded	15 (3%)	203 (37%)	168 (30%)	110 (20%)	37 (7%)	11 (2%)	9 (2%)	3 (1%)
Abnormal investigation result is not reviewed	35 (6%)	171 (31%)	139 (25%)	125 (22%)	62 (11%)	10 (2%)	10 (2%)	4 (2%)