## eTable1: Full data extraction table of included articles

Author, Year	Study Design, Sample Size, Country	Barriers to Incident Reporting	Facilitators of Incident Reporting	Negative cases (No impact)
Albolino et al., 2010 <sup>(1)</sup>	Questionnaire based-study 820	Fear of mistrust in colleagues		
	Italy	Not considered a priority		
		Fear of punishment		
		Does not help to improve safety		
		Lack of time		
Alsafi et al., 2011	Questionnaire based-study. 107	Not my responsibility		
	Saudi Arabia	I do not want to lose my good relationship with my colleague		
		I might be reported by my colleague in turn		
		No incentive to error disclose		
		Avoiding punishment		
		Avoiding damage to reputation		
		It will not be discovered		
Anderson et al., 2013 (3)	Semi-structured interviews and documentary analysis	Experienced in using IR systems (Mental health staff)		

	62 United Kingdom	Blame culture (mental health staff)	
Arfanis et al., 2012	Semi-structured interviews 48 United Kingdom	Not used as learning tools to prevent similar occurrences elsewhere.  Pressures on time  Resources  A lack of faith in the established system  Fruitless and often pointless exercise that has little or no impact on improving patient safety and welfare  Fear of litigation  Fear of disciplinary action  Blame  The availability and ease of identifying the information  No feedback	Feedback Learning and improvement Anonymous web based forum as an add on to IR system
Armitage et al., 2010 <sup>(5)</sup>	Semi-structured interviews and retrospective review of error reports	Lack of feedback	

	United Kingdom		
Ashcroft et al., 2006 <sup>(6)</sup>	Questionnaire-based Study 275 United Kingdom	Local reporting  Good patient outcome less likely to be reported than poor or bad patient outcome.  Compliance with a protocol less likely to be reported than a violation or error.  'Fault-led' attitude  One-off situations by individuals not report  Loyalty to colleagues  National reporting system  Confidence in National Patient Safety Agency	Local reporting  Poor or bad patient outcome more likely to be reported than good patient outcome  Violation of protocol or error more likely to be reported than compliance with protocol.  'Learn from mistakes' culture  Individuals making continual mistakes  National reporting system
Backstrom et al., 2000 <sup>(7)</sup>	Questionnaire-based study. 748 Sweden	Assessment that the reaction is already well known  Forgetting to report	

Rallangrud et al	Ouestionnaire-based study	Hesitance to report on suspicion  Lack of time  Giving preference to other matters  Uncertainty about the existing rules for reporting  Difficulty in finding the right form		Organisational
Ballangrud et al., 2012 <sup>(8)</sup>	Questionnaire-based study. 220 Norway	Supervisor/manager expectations, actions promoting safety  Feedback and communication about error		Organisational learning and continuous improvement  Teamwork within hospital units  Communication openness  Non punitive response to errors  Staffing
Bateman et al., 1992 (9)	Questionnaire-based study. 1181	One case cannot contribute to medical knowledge	Should be financially	

	United Kingdom		reimbursed
	- Critica ranguom	Impossible to determine responsible drug	Would report if easier method
		Serious ADRs well known when the drug is marketed	easier metriou
		Professional obligation	
		Reporting increases personal liability	
		Reporting results by badgering by Committee of safety of medicines	
		Takes too much time to ADR report	
Bawazir et al., 2006 <sup>(10)</sup>	Questionnaire-based study. 172	No reporting forms available	An obligation to do so
	Saudi Arabia	Reporting address unknown	There was a fee
		Reporting form too complicated	
		Reporting ADRs is too time	Saw colleagues doing so
		consuming	Attention drawn by
		All ADRs are known	publication
		Want to publish myself	Receiving feedback
		Confidentiality	Report through the internet
		Patient confidence	

		Difficult to admit harm to patient	
		Reporting could show ignorance	
		Fear of liability	
		No motivation	
		Insufficient clinical knowledge	
		Do not know how to report	
		Causality uncertain	
		One report make no difference	
Beasley et al., 2004 (11)	Focus groups	Punitive system	A feedback system
2004 (17)	14 United States of America		for submitters is
	Officed States of Afficia		necessary to maintain interest.
			mamam merest.
			Safe and secure
			access
			There needs to be
			easy access
			What to report
			needs to be clearly
			defined
			The reporting forms

			must be simple
			Error reporting must fit into a clinicians current work flow  A non-punitive system is essential  Reporter should only be required to report once if there are multiple systems
Belton et al., 1995	Questionnaire-based study 284 United Kingdom	Report forms are not available when needed  Doctor does not like reporting confidential information  Doctor unsure how to report an ADR  Doctor fear he/she may appear foolish about reporting a suspected reaction  Doctor fears he/she may be exposed to legal liability by reporting reaction  Doctor too busy to send an ADR	

		report	
		Doctor is reluctant to admit he/she may have caused a patient harm  Doctor would rather collect and publish personally  Doctor believe that only safe drugs are marketed	
Belton et al., 1997	Questionnaire-based study Sample size not reported International: Denmark, France, Ireland, Italy, Netherlands, Portugal, Spain, Sweden, United Kingdom	Telephone number unavailable Report forms unavailable Address of reporting agency unavailable Unsure how to report Patient confidentiality Worried about appearing foolish Worried about legal liability (Not Denmark or Spain) Too busy to report ADRs Reluctant to admit they have caused a patient harm	Worried about legal liability (Not Denmark or Spain)  Ambition to publish a personal series of cases (Not Spain, Sweden or Portugal)  Patient confidentiality (Not Spain)

		Ambition to publish a personal series of cases (Not Spain, Sweden or Portugal)  Believes that all marketed drugs are safe	
Blegen et al., 2004	Questionnaire-based study 1105	Administrative response	
	United States of America	Personal fear	
		Quality management	
		Staffing resources	
		Physical resources	
		Peer relations	
		Job satisfaction	
Braithwaite et al., 2010 (15)	Questionnaire-based study. 2185	IIMS training	Form of training received
2010	Australia	Accessibility of reporting system	received
		Security of IIMS	
		Feedback from reports	
		Workplace reporting culture	
		Value placed on IIMS	

Chang at al	Ougationnaire based study		Lovel of ourse out	٨٥٥
Chang et al., 2012 <sup>(16)</sup>	Questionnaire-based study 183 Taiwan		Level of support	Age
Chiang et al., 2006	Questionnaire-based study. 597	Being blamed for MAE results		
	Taiwan	Adverse consequences from reporting		
		Patient's negative attitude		
		Physicians' reprimand		
		Not recognised MAEs occurred		
		Being recognised as incompetent		
		Too much time for filling reports		
		Think MAEs not important enough to be reported		
		Too much time for contacting physicians		
		Unclear MAE definition		
		Disagreement over MAE		
		Unrealistic expectation for administering drugs correctly		

Chiana at al. 2010		No positive feedback  Much emphasis on MAE as nursing quality provided  Focus on individual rather than system factors to MAEs  Administrators' responses to MAEs do not match the severity of the errors	Comparations	
Chiang et al., 2010	Questionnaire-based study 838 Taiwan	Experience of making MAEs  Nursing professional development  Fear	Same attitude towards self and co-workers  MAE reporting rate  Nursing quality	Age  Management and leadership  Administrative barriers  Reporting process
Chiang et al., 2012	Questionnaire-based study 1049 Taiwan		High scores on the safety organising scale  Tenure of present position  Self-evaluated IR rates	

			Those more willing to report their own incidents are more likely to report coworkers incidents	
Church et al., 2013	Questionnaire-based study 546	Hierarchical structure		
	United States of America	Poor communication		
		Fear of reprimand		
		Reprimand of other therapists and dosimetrists		
		Personality		
		Lack of reporting system		
Clark et al., 2013	Questionnaire-based study 228	Fear of being judged by colleagues		
	International: Australia and New Zealand	Personal Guilt		
	140W Zodiana	Feel it as unnecessary		
		Near misses are part of life		
Coley et al., 2006	Focus groups 8	Time consuming		
	United States of America	Inadequate staffing		

Cosentino et al., 1997 (23)	Questionnaire-based study 207	Reaction not clinically relevant		
1007	Italy	Awareness of similar reactions		
		Unavailability of report forms		
		Doubtfulness about which ADRs should be reported		
		Confidence about ADRs being well documented before marketing		
		Ignorance about reporting procedures		
		Too much time required to fill in the report form		
		Don't feel obliged to report		
		Don't want to create undue alarm		
		Uselessness of ADR spontaneous reporting		
Covell et al., 2009	Semi-structured interviews and questionnaire based study 50 Canada	Adverse consequences		
Daly et al., 2005	Questionnaire-based study 598	Administrators' length of time in position	Directors of nursings'	Administrators' knowledge of

	United States of America		knowledge of the	low
	United States of America	Administrate and an I Discrete with a	knowledge of the	law
		Administrators' and Directors' length	law in of nursing	
		of time in facility		Administrators'
			Administrators'	belief that
		Administrators' length of time in	level of education	'elders are able
		profession		to get help if
				they need it'
		After internal investigation abuse		
		was thought not to exist		Age of
		The area grammes to exact		administrators
		Told not to report the abuse by my		and directors of
		boss		nursing
		0000		Director of
		Departed obuse in the past and IDIA		
		Reported abuse in the past and IDIA		nursings' length
		did nothing		of time in
				position
		Reported abuse in the past and it led		
		to a bad outcome		Director of
				nursings' length
		Reported abuse in the past and IDIA		of time in
		ruled it out		profession
				Director of
				nursings' level
				of education
				3. 344341011
				Administrators'
				knowledge of
				the law in
				nursing
Davies et al., 2012	Focus groups	Lack of feedback		
Davies et al., 2012	Focus groups	Laur UI IEEUDaur		

(26)	19 International: United		
Ehrenpreis et al., 2012 (27)	Kingdom/Uganda Questionnaire-based study 92 United States of America	Unsure how to report appropriately  Did not see adverse events on a regular basis  Too busy to make reports  The existing method was too cumbersome  Voluntary reporting was not an important process	Easier to use
Eland et al., 1999	Questionnaire-based study	Uncertain association	
(28)	1357 Netherlands	Too trivial to report	
		Too well known to report	
		Unaware of the existence of a nation ADR reporting system	
		Unaware of the need to report ADRs	
		Did not know how to report ADRs	
		Too bureaucratic	
		Not enough time	

			<del>                                     </del>
		Concerned that the report could be used in legal case for damages by the patient	
		If another physician had prescribed the medicine	
		Medication brought over counter rather than prescribed	
Elder et al., 2007 (29)	Focus groups 139	Burden of effort	Perceived benefit of reporting –
	United States of America	Lack of time	learning and improvement
		Forgetfulness	Emotional benefit
		Information not readily available	Guilt
		Computer problems	Personal
		Online access	responsibility
		What to report	Anonymous
		Who should report	reporting
		What is an AE	Easing the burden of reporting
		What information is needed	The more harm, the more likely to
		Common problems	report

		Rare errors	
		Less serious errors unlikely to be reported	
		Feeling personally responsible	
Elder et al., 2008	Focus groups and questionnaire-based study	Too busy with other activities	Asked by management to
	125 United States of America	Didn't reach the patient	make specific reports
		Risk of harm is none or little	Harm actually
		Error made my someone new-give them a break	occurred
		Feel worse emotionally	Risk of harm is great
		Feel like a failure	Error made by
		Fear punishment	someone unable to be spoken to one-
		Blame	to-one
		Name on permanent record	Feel better emotionally
		Risk losing friends	Outlet for irritation at situation or
		Will make enemies on unit	person
		No feedback so no personal benefits	Honesty is a virtue

			Get a "there but for the grace of god" understanding Improve clinical
			Could be a learning experience for others
			No known penalty for making a report
Erler et al., 2013	Questionnaire-based study 51 United States of America		Higher levels of teamwork
			Communication openness
			Perception of manager actions promoting safety
Espin et al., 2010	Semi-structured interviews	Did not feel it was an error	Patient negligence
(32)	37 Canada		Threat of potential or actual harm to the patient
			Patient advocacy

			Following proper procedure  Error prevention  Learning opportunities
Espin, et al., 2007	Semi-structured interviews 13 Canada	Domain-specific expertise is a necessary pre-requisite for reporting the error  Part of the surgeon's responsibility as it fell within the surgical scope of practice.	Events outside of professional boundaries were more likely to be reported  Responsible for error
Espin et al., 2006	Semi-structured and structured interviews 28 Canada	Responsibility	
Evans et al., 2006 <sup>(35)</sup>	Questionnaire-based study 773 Australia	I never get any feedback on what action is taken  I don't feel confident it is kept anonymous  The incident form takes too long to fill out and I just don't have time  I am worried about litigation	

The incident was too trivial	
When the ward is busy I forget to make a report	
It's not my responsibility to report someone else's mistakes	
I don't know whose responsibility it is to make a report	
I don't want to get into trouble	
When it is a near miss, I don't see any point in reporting it	
Even if I don;t give my details, I am sure that they'll track me down	
The AIMS+ form is too complicated and requires too much detail	
Junior staff are often blamed unfairly for adverse incidents	
I wonder about who else is privy to the information that I disclose	
If I discuss the case with the person involved nothing else needs to be done	

		I don't want the case discussed in meetings  I am worried about disciplinary action  Adverse incident reporting is unlikely to lead to system changes		
		My co-workers may be unsupportive		
Fairbanks et al., 2008 (36)	Interviews, focus groups and events reports from an	Blame and Shame	Non punitive system	
	anonymous system	Punishment		
	United States of America	Legal factors		
		Reluctance to tell on colleagues		
Fukuda et al., 2010	Questionnaire-based study		Decreased time for	Non-punitive
(37)	Sample size not stated		reporting (nurses	policy
	Japan		and physicians)	(physicians/nur ses)
			Electronic reporting	333)
			(physicians)	Rate of
			Attendance at	recommendations derived from
			educational	reported
			seminars	incidents
			(physicians)	(physicians/nur ses)
			Hospital size	
				Electronic

	Ţ		
		Ownership –	reporting
		university hospital	(nurses)
		(physicians)	
		Ownership –	Attendance at
		national hospital	educational
		(nurses)	seminars
		(1101303)	
		Accionment of	(nurses)
		Assignment of	Clama a di constitut
		patient safety	Elapsed years
		manager	of incident
		(physicians)	reporting
			system
			(physicians
			and nurses)
			,
			Attendance at
			conference
			(Physicians/nur
			ses)
			14411
			Ward rounds
			(Physicians/nur
			ses)
			Ownership –
			university
			hospital
			(nurses)
			(1141000)
			Ownership –
			national

				hospital (physicians)  Ownership – municipal + public hospitals + healthcare corporation + other (physicians/nur se)  Assignment of patient safety manager (nurses)
Gaal et al., 2010	Observational study Sample size not stated International: Austria, Belgium, England, France, Germany, Israel, The Netherlands, Slovenia, Switzerland, and Wales		Group (>3) practice	Practice setting  Amount of responsibility  Hours of work  Physical working conditions  Single+ dual practice
Garbutt et al., 2007	Questionnaire-based study	Private practice	Belief that errors	Perceived risk

(39)	557 United States of America	are one of the most serious issues in healthcare	for personal malpractice risk
		Belief that they should report serious errors	Personal involvement in an error
		Belief that they should report minor errors	
		Belief that they should report near misses	
		System change to improve patient safety after errors reported	
		If error was caused by system rather than individual failures	
		Personal involvement in serious errors	
		Assurance that the information was	

Generali et al., 1995 <sup>(40)</sup>	Questionnaire-based study 235 United States of America  Questionnaires and semi-	Unsure drug caused reaction  Do not have forms  Do not know how  Reaction was expected  Reporting would not occur to me  Fear of legal liability  Not my responsibility  Hours worked per week (>49 or <40)  Fear of management reaction	A non-punitive reporting system  A process that takes less than 2 minutes to use  Local to the clinician's unit or department  Hours worked per week (43-49 hours)  Work setting	Age Gender Number of years in practice
(41)	structured interviews 107 United Kingdom	Todi oi management reaction		

Green et al., 1999	Structured interview 30	Lack of time/too busy	Certainty of ADR
	United Kingdom	Well recognised reaction	Suspicious of a reaction
		Limited time to spend with patients	Training
		Lack of motivation	Fee for reporting
		More information about ADR needed	Access to patient
		Lack of confidence in making report	records
		Patient confidentiality	Feedback
		Patient suffered an ADR to a product counter prescribed by the pharmacists being interviewed	More time
Green et al., 2001	Questionnaire-based study 322 United Kingdom	Concern that a doctor gets a copy of reporting form	Reaction is of a serious nature
	Office Kingdom	Lack of confidence in discussing the ADR with the prescriber	The reaction is unusual
		Apprehension about sending in an inappropriate report	The reaction is to a new product
		Lack of time to fill in a report	Certainty that the reaction is a ADR
		Concern that a report will generate extra work	The reaction is well

	recognised for a
The absence of a fee for reporting	particular agent
ADRs	
	Education/training/
Lack of time to actively look for	study days or
	1 1
ADRs while in clinical practice	evenings
Lack of clinical knowledge makes it	More time to spend
difficult to decide whether or not an	on wards with
ADR has occurred	patients
Don't feel the need to report well	More feedback,
recognised reactions	reminders and
	increased
Reporting cards not available when	awareness
needed	dwaronooo
needed	Encouragement
	Encouragement
	from managers and
	departments
	Increased
	collaboration with
	prescribers and
	participation on
	ward round
	Increased
	accessibility of
	reporting cards
	reporting cards
	Cords apositically
	Cards specifically
	designed for the

use of pharmacists
More publicity in journal about reporting scheme
Online access or telephone based reporting
Development of local incentives
Increased confidence in dealing with medical staff
Making reporting a professional responsibility
A fee for reporting
ADR specialist pharmacists
Increasing awareness among other professionals that pharmacists could report ADRs

van Grootheest et al., 2002 (44)	Questionnaire-based study 147	Causality uncertain	Feedback	Reporting could show
31., 2002	Netherlands	Too time-consuming	Publications	ignorance
		No reporting forms available	Information about the national centre	
		Reporting address unknown		
		Reporting form too complicated	Simplification of reporting procedure	
		All adverse reactions are known	Promoting reporting as part of	
		Want to publish myself	professional duty	
		Confidentiality	Financial compensation	
		Fear of liability	Mana attantian ta	
		No motivation	More attention to ADR reporting in university	
		Insufficient clinical knowledge	curriculum	
		Do not know how to report	Database of national centre available on the internet	
			Compulsory reporting	
			Peer reporting	

Haines et al., 2008	Questionnaire-based study 212	Time	Staff believe that completing IRs
	Australia	If the ward is very busy	improves patient safety
		Patients' responsibility for adverse	
		events	Staff belief that competing IRs
		Cause of the incident	protects against legal liability
		Other methods of documentation	If the patients was
		Access to previous reports (non filing of incident reports in the notes)	harmed/injured
		, ,	Patient factors
		Poor user friendliness of computer reporter systems	Protect staff
		Made staff feel personally responsible for the form	Type of incident - preventable
		Poor access to computers	
		Non reporting by role models	
		Absence of a definition of a fall	
		Blame	
		Absence of training	

Handler et al.,	Focus group and	Lack of readily available medication	
2007 (46)	questionnaire-based study 132	error reporting system or forms	
	United States of America	Lack of information on how to report a medication error	
		Lack of feedback to the reporter or rest of facility on medication errors that have been reported	
		Lack of knowledge of which medication errors should be reported	
		Systems or forms used to report medication error are long and time consuming	
		Lack of knowledge of the usefulness of reporting medication errors	
		Lack of a consistent definition of a medication error	
		Lack of an anonymous medication error reporting system	
		Lack of recognition that a medication error has occurred	
		Lack of a culture of reporting medication errors	

		Extra time involved in documenting a medication error	
		Fear of disciplinary action	
		Fear of being blamed	
		Fear of liability or lawsuits	
		Not knowing who is responsible for reporting a medication error	
		Belief that it is unnecessary to report medication errors not associated with patient harm	
		Lack of recognition of the actual or potential harm of a medication error	
		Belief that reporting medication errors has little contribution to improving the quality of care	
		Difficulty in proving that a medication error actually occurred	
		Fear of losing respect of co-workers	
Hartnell et al., 2012	Focus group and semi- structured interviews	Extra time required to report	Improved care/improved
	30 Canada	Extra work required to report	patient safety

Cumbersome IR forms  Hesitancy about 'telling on' someone else  Fear of loss of reputation/perceived incompetence  Perceived severity of error (less severe errors are less likely to be reported)  Inability to recognise or identify medication errors  Lack of definitions or standards for reporting  Lack of belief that reporting makes a difference  lack of trust about how error reports will be used  Reporting is the responsibility of someone else	To prevent patient from receiving wrong medication  Provides immunity/protection from legal action  Fear of censure (harsh criticism or blame)  Perceived severity of error (more severe errors are more likely to be reported because a report will be expected)  Follow rules or policies  Ensures accountability
Reporting is the responsibility of	
Fear of reprisal from management/administration	
Fear of exposure to malpractice suits	

Hasford et al., 2002 (48)	Questionnaire-based study 588 Germany	ADR too well known  ADR too trivial  Uncertain causality  Reporting too bureaucratic  Lack of time  Rules of conduct unknown  Suspect that drug prescribed by colleague  Reporting process unknown  Lack of financial reimbursement  Suspect drug was self-medication  Reports considered useless  Reporting system unknown  Fear of legal liability  Non-serious adverse reaction to	Serious unknown ADR to a new drug Serious unknown ADR to an established drug Serious known ADR to a new drug	
Heard et al., 2012	Questionnaire-based study 433	I am worried about litigation		Generalised de-identified

Australia	I don't want to get into trouble	feedback about
		reports
	My colleagues may be unsupportive	received from
		the anaesthetic
	I am worried about disciplinary action	community
	I may be blamed unfairly for the	Role models
	event	e.g. senior
		colleagues and
	I do not want to be discussed in	department
	meetings.	directors who
	Adverse events reporting makes little	openly encourage
	contribution to quality care	reporting
	John Marie Control of Grand Control of G	
	I don't know whose responsibility it is	Legislated
	to make a report	protection of
	A good outcome of the case makes	information you provide from
	A good outcome of the case makes reporting unnecessary	use in litigation
	Toporting dimesessary	doo iii iiigatioii
	I do not know which adverse events	Ability to report
	should be reported.	anonymously
	From if I don't nive new data its line	01
	Even if I don't give my details I'm worried they will track me down	Clear guidelines
	womed they will track the down	about what
	The forms take too long to fill in and	adverse events
	just don't have time	are errors to
		report
	When I am busy I forget to make a	L.C C
	report	Information on

	how
I don't feel confident that they	confidentiality
information I provide will be kept	will be
confidential	maintained if
Cormacritical	you supply
I never get any feedback after I	your name
report an adverse event	your name
roport air aaverse event	Individualised
I wonder about who else will have	feedback to
access to information I disclose	you about
access to information raisclose	reports you
As long as the staff involved learn	submit
from incidents it is unnecessary to	Submit
discuss them further	Paper forms for
discuss them further	reporting
I would protect my self-interests	provided in
ahead of the interests of the patient if	each theatre
I could (by hiding or denying error)	each theatre
1 codid (by fliding of deflying error)	More support
Competition with my peers could	from
prevent me from disclosing an error	colleagues
prevent the north disclosing an end	colleagues
If a doctor is careful enough he or	Less blame
she will not make an error	attached to
Sile will not make an end	those who
It would affect my identity as a doctor	report errors
to admit to an error	report errors
to admit to an end	ANZCA
Other don't need to know about	continuing
errors I have made	professional
GITOTS I HAVE HIAUE	development
Disclosing an error, if you don't have	point for
Disclusing an endi, if you don't have	point for

to, is an optional act of heroism	reports.
I would cover up an error I had made	Access to
if I could	computer
	based
If I admit to an error I will feel like a	reporting
failure	systems for
	home
It would affect my self-esteem to	
admit to an error	Education
Destar la mala conserva	about the
Doctors who make errors are	purpose of
humiliated my their colleagues	reporting
Medicine has a culture of silence	Computer
where errors are not talked about	based
	reporting
Doctors who make errors are blamed	systems
by their colleagues	
	Training on
Doctors should not make errors.	how to use
	computer
	based system
	Training on
	how to fill in
	papers forms
	for reporting
	Payment for
	time taken to
	report

Herdeiro et al., 2006 <sup>(50)</sup>	Questionnaire-based study 256	Lack of time	Workplace (hospital	Gender
2006 (50)	256 Portugal	Complexity of reporting	(hospital pharmacists more likely to report than community pharmacists)  Really serious ADRs are not well documented by the time a drug is marketed'  Serious and not expected ADRs	Age  Job function (registered, assistant or other pharmacists)  Possible to determine if a drug is responsible for a particular adverse
			Report an ADR if I were unsure that it was related to the use of a particular drug	reaction' Cannot contribute to pharmaceutica knowledge
				Interested in articles about ADRs'
				Most correct way to report ADRs in is the pharmaceutica

		literature
		orataro
		Financially
		reimbursement
		for providing the ADR
		service
		Professional
		obligation to
		report ADRs
		Reporting
		ADRs puts
		career at risk
		I do not have
		time to
		complete the
		report card
		I do not know
		how the
		information in
		the report card
		is used
		I talk to
		pharmaceutical
		companies
		about possible
		ADRs with their

				drugs
Hohenhaus et al., 2008 (51)	Questionnaire-based study 175 United States of America	Afraid to report a medical error they had made	Error resulting patient harm	
	Office States of Afficia	Afraid to report a medical error made by someone else	Error by novice nurse	
		Might not report if there was no harm to the patient and the error was recognised quickly		
		Might not report if a physician told them not to report the error		
		Would not report if their supervisor told them not to		
Holmstrom et al., 2012 (52)	Questionnaire-based study 16	Fear of consequences	Provides opportunity for	Paper-based
	United Kingdom	Culture of blame	evaluating causes of errors (e.g. root	Quick and easy to use
		Lack of training in MER for health- care professionals	cause analysis)	
		Lack of time for reporting	Uses a non- punitive approach to reporting	
		Lack of organizational leadership and support	Provides feedback of results of error	
		Lack of legal protection for individual health-care professionals who have	analysis for those involved in	

made an error	reporting
Lack of understanding why reporting is needed	Easy to use Provides
Concern that no beneficial action will follow	opportunity for error data analysis
Non-anonymous reporting	Produces recommendations
Perceived to be bureaucratic	and guidelines for improving
Lack of health-care staff	medication safety
Lack of financial resources	Drovidos
	Provides confidentiality of reported information
	Provided and maintained by one national organisation
	Integral part of patient safety reporting system
	Reporting of errors is voluntary

		Reporting of errors is mandatory  Allows all healthcare professionals to report errors  Available in electronic format  Independent reporting system dedicated for medication error reporting  Provides a choice of reporting anonymously  Includes reporting of both potential and actual errors.	
		and actual errors	
Hutchinson et al., 2009 (53)	Retrospective analysis of routinely collected data and questionnaire-based study Sample size not stated United Kingdom	Employer treats fairly staff involved in error near miss or incident	Knows how to report errors, near misses and incidents
		Employer encourages staff to	When errors are reported,

			report errors, near misses or incidents  Employer treats reports of errors, near misses or incidents confidentially  Employer does not blame or punish people who make errors.  Access to a counselling service were also more likely to report.  Previous reporting behaviours  Level of risk management	employer takes action to ensure that they do not happen again
Irujo et al., 2007 (54)	Case control study 78	Not serious ADR		Age
	Spain	Already well known ADR		Working experience as
		Uncertain about causality		pharmacist
		Forgot to report		Participation in

	Lack of time	a programme for detection and resolution of DRPs
		Education on detection and resolution of DRPs
		Frequently considering the possibility of finding an ADR when attending a patient with symptoms
		Forgetting to report
		Education for ADR reporting
		Awareness of the importance of reporting system
		It is necessary to be sure that the reaction is

				causally related to the use of a particular drug  Basic knowledge about ADR reporting
Jeffe et al., 2004 (55)	Focus groups 109 United States of America	Not knowing what to report  Errors that pose little risk to the	Severity of the situation (nurses)	
	Officed States of Afficia	patient	Likelihood of	
		patient	reoccurrence	
		Errors that do not end up harming the patient	(nurses)	
			Severe events	
		Not knowing how to report	reported as the error would be	
		Fear of disciplinary repercussions (nurse and physicians)	'found' out anyway	
			Self-protection	
		Fear of legal repercussions (nurse		
		and physicians)	The importance of	
		Fear of repercussions from doctors	reporting errors for educational	
		(nurses)	purposes	
		Link between reporting and performance reviews (nurses)	Anonymous (physician and nurses)	

		Protecting colleagues from disciplinary action(nurses)  Lack of confidentiality	Simple (physician and nurses)  Fast reporting
		Name, blame, shame culture	procedures(physici an and nurses)
		Fear of public exposure	Receipt of critical
		Staff shortages	feedback about the errors
		Lack of time	Anonymous, phone
		The lack of simple procedure for reporting errors	in system (physicians)
		Lack of feedback	Educational rather than punitive system (physicians)
			System that was 'lawyer proof'
			Blame free reporting (nurses)
Jennings et al., 2011 <sup>(56)</sup>	Focus groups, interviews and questionnaire based study Sample size not stated Australia	Burden of reporting in terms of time  Lack of accessibility of reporting forms	Clarity of indemnity from prosecution

		Time elapsed following incident	
		Priority of reporting over other work tasks	
		Forgetting to report	
		Workload	
		Fear of disciplinary action	
		Fear of potential litigation	
		Fear of breaches of confidentiality/anonymity	
		Fear of embarrassment within peer group	
		Fear that incidents many impact on their likelihood of promotion	
		Concern that nothing would change even if the incident was reported	
		Lack of familiarity with process	
Johnstone et al., 2008 (57)	Focus groups, semi- structured interviews and questionnaire-based study 35	Frequency of incident-more frequent less likely to report	Seniority of graduate nurses

	Australia			
Joolaee et al., 2011 (58)	Questionnaire-based study 286 Iran			Perceived work conditions
Kagan et al., 2008	Questionnaire-based study 201 Israel	The practice of ward nurse managers to cover up error, that is dealing with the error themselves without reporting to a higher authority	How the ward's and hospital's dealt with medication error  How their ward handles error reporting	
Kagan et al., 2013 (60)	Questionnaire-based study 247 Israel	Medical error incidence	Patient safety culture index  PSC at organisational level  PSC at departmental level  PSC at respondents personal performance level  Nurses' place of birth and their professional status (academic or nonacademic	

			registered nurse)
Kaldjian et al., 2009 <sup>(61)</sup>	Questionnaire-based study 338 United States of America		Feedback
Karsh et al., 2006	Focus group 14	Length of report	Feedback
	United States of America	Punishment	Mandatory system
		Reporting near misses	Financial incentives
			Other incentives (protection from malpractice and disciplinary action)
			Support in using system
			Education in using system
Kennedy et al., 2004 <sup>(63)</sup>	Questionnaire-based study 113	Not their responsibility to report	
	United States of America	Never thought to report/not required to do so	
		Handle errors internally i.e. no corporate system	
		No errors worth reporting	

		No time to report  Forms not available or convenient	
Khan, 2013 <sup>(64)</sup>	Questionnaire-based study 50 Saudi Arabia	Unavailability of professional environment to discuss ADR	
	Gaddi Afabia	Reporting forms are not available	
		I do not know how to report	
		Reporting forms are too complicated	
		Reporting is time consuming	
		I am not motivated to report	
		I fear legal liability of the reported ADR	
		I am not confident whether it is an ADR	
		Insufficient knowledge of pharmacotherapy in detecting ADR	
		Belief that only safe drugs are marketed-not cause of reaction	
King et al., 2006	Questionnaire-based study 39	Time constraints	

	United States of America	Difficulty locating forms	
		Lack of closure/feedback	
		Not important	
		Fear of disclosure to risk management	
Kingston et al., 2004 <sup>(66)</sup>	Focus groups 33 Australia	Lack of knowledge about the reporting process and	Effective and efficient IRS
	Additional	Lack of knowledge about what constitutes an incident	IRS with threat or blame
		"Nursing form" by association (not identified as being part of doctors role)	Prompt, relevant feedback
		Time constraint	IRS that drive improvements
		Complexity of reporting form	Monetary payment
		Lack of feedback	Simplification
		Lack of legal privileges afforded to the reporting process	Less time consuming
		Culture of blame	Clear definitions of what constitutes an
		No value	adverse event/near-miss

			Evidence of value of IRS
			Reporting process to be made more relevant to doctors
			Reporting process less threatening by renaming the form
			Increased awareness and knowledge of IR process
			Protection from liability
			System that doesn't require input from doctors (nurses)
			Education at orientation (nurses)
			Anonymous reporting
Kreckler et al.,	Questionnaire-based study	I am too busy to fill out the form	

2009 (67)	137		
	United Kingdom	The form takes too long to complete	
		,	
		I am worried about litigation	
		I do not want the case discussed in meetings	
		I never get any feedback	
		It makes little contribution to the quality of care	
		I am not sure what incidents to report	
		The incident was too trivial	
		The incident did not result in any harm	
Li et al., 2004 (68)	Questionnaire-based study	Address of reporting agency not	Increasing
	1653	available	awareness among
	China		administrators,
		Report forms unavailable	doctors & nurses
		Reporting process unknown	Establishing ADR institutes
		Unaware of a national ADR reporting	
		system	Education and
		Deticut confidentiality	training in ADR
		Patient confidentiality	knowledge and related topics
	<u> </u>		Totatod topios

	1	Tara bassas ta manant ADD	
		Too busy to report ADR	
		ADR sufficiently well documented	
		Reluctant to admit that they have caused a patient harm	
		Worried about feeling foolish	
		Reluctant to admit they may have made a medical error	
		Personal ambition to publish a case study	
Martowirono et al., 2012 (69)	Focus group 22	Negatively valued	Reporting process- ability to report
	Netherlands	Costs time	over the phone or send an email
		Perceived as another administrative	
		task that they have to complete	Anonymous reporting
		Priority	
		,	Provide the
		Do not always agree with the	possibility to report
		definition of incident	without identifying
			the person involved
		Incidents that had no major patient	Dura del a fa a ella a ella
		consequence	Provide feedback
		Incidents that have happened before	Provide feedback
		and has already been reported	to the reporter if an

	[
	incident on how the
Incidents that was not preventable	report will be
	handled
The cause of the incident Is already	
clear	Feedback-
	communicate the
Incidents is unlikely to happen again	results in terms of
	systems changes
Was not an incident but a	
complication	Create an incident
·	reporting culture
Incident already been discussed with	'
the people involved	Create a culture in
	which IR is less
The lack of feedback on a report	emotionally
The fact of recall and report	charged e.g. by
Absence of visible system changes	systematically
were also issues	discussing IR
were also issues	within a ward and
Disloyal to colleagues	stimulating role of
Disioyal to colleagues	supervisors
Not their responsibility	Supervisors
Not their responsibility	Cimplify the
le sel liebility	Simplify the
legal liability	procedure
Unpleasant working conditions	Design a procedure
Supressaint Working Containons	in which it is
Lack of encouragement from	possible to only
superiors to report incidents.	report the
Superiors to report including.	essentials of an
Incident reporting is emotionally	incident, e.g. by
	making a call or
charged	making a call of

Married all 10004		Some residents stated that they did not complete IR because they did not think of it whereas others said  Did not know what to report.  Did not know how to report  IRS complicated  Workload	filing out a card or compact form with standard incidents. If necessary, the resident can be contacted for more information  Make it easy for a resident to find out if an incident has already been reported  Clarification what to report  Clarification about and how to report  Excite residents to report  Draw attention to IR e.g. putting up posters with a catchy slogan
Mayo et al., 2004	Questionnaire-based study 983 United States of America	Afraid of manager reaction  Afraid of co-workers' reactions	

		Not thinking an error was serious enough	
		Fear of disciplinary action	
McArdle et al., 2003 (71)	Semi-structured interviews 15	It takes too long	
	United Kingdom	Lack of feedback received	
		Lack on incentive	
		Cumbersome	
		Non-anonymous	
		Fear of blame	
		Description of medication did not fall into IRS formats-scope of reporting	
Merchant et al., 2005 (72)	Questionnaire-based study 207	I think of reporting too late	Unnecessary as anesthesia
2000	Canada	Don't know where CIRS forms are	is safe
		Fear of lawyers getting information	futile as anesthesia is
		I don't know what sort of incident to report	safe
		I'm too busy	
		Fear of record of problem	

		Don't have CIRS forms	
		My incidents are too minor	
		Too long	
		No value will come of this	
		Too much writing	
		Incidents I see are other's problem	
		Too many tick boxes	
		Unsure what 'critical incident' is	
		Effort is doomed to failure	
		Too difficult	
		Form is confusing	
		Unimportant to me	
		Nothing can be learned from me	
		CIRS asks wrong questions	
Mrayyan et al., 2007 (73)	Questionnaire-based study 779	Fear of disciplinary action/lose job	
	Jordan	Errors not serious to warrant	

		reporting  Fear of reaction from co-workers  Fear of reaction from nurse managers		
Mustafa et al., 2013 <sup>(74)</sup>	Questionnaire-based study 136 Pakistan	Uncertain association  Awareness  Concern about legal liability	Seriousness of ADRs  Unusual reaction  Reaction to a new product  Confidence in the diagnosis of ADR	
Naveh et al., 2006 (75)	Questionnaire-based study 632 Israel	Perceived safety procedures	Perceived safety information flow	Perceived priority of safety Unit type
Okuyama et al., 2010 <sup>(76)</sup>	Questionnaire-based study 430 Japan		Safety management at ward level	Safety management at the hospital level  Attitudes of ward safety managers

Osborne et al.,	Questionnaire-based study	Error not serious		Perceptions of
1999 <sup>(77)</sup>	57			medication
	United States of America	Afraid of repercussions		errors
		Afraid of reactions from		
		managers/co-workers		
Parvizi et al., 2014	Questionnaire-based study	Did not know they were expected to	Better education of	
(78)	119	do this	the means of	
	United Kingdom	Did not know how to report to MHPA	adverse IR	
		Did not know how to report to MHRA	Improvements in	
		I do not see the purpose of reporting	the feedback sent	
			to the reporter on	
		Lack of time	the outcomes of the adverse	
		Blame	incidents	
		Direct reporting to the manufacturer	Improvements in the guidance on	
		Not reporting if the types of device	the type of adverse	
		failure were considered to be common knowledge	device related incidents to report	
		Reporting only those that were	Improvements in	
		unexpected failures or failures that	the electronic	
		may affect the patient or user	means of adverse IR	
		Reported by either a nurse or other		
		doctor	Improvements in	
			the clinical and	

			adverse incidence governance
Patrician et al., 2009 (79)	Questionnaire-based study 43 United States of America	Perceptions that the administration focuses on the individual and not the system	
		Nurses are blamed when something bad happened to patients	
		Fear adverse consequences for reporting errors	
		Nurses believe that their peers will think them incompetent	
		Nurses do not think the error was important enough to report	
		Fear of administrative response	
		Disagreement over error	
		Reporting effort Lack of agreement about definition of error	
		Lack of error recognition Excessive length of time for contacting physician	
Rasmussen et al.,	Questionnaire-based study		Safety climate

2014 <sup>(80)</sup>	124 Denmark		Team climate Inter-departmental working relationships Increased cognitive demands	
Rogers et al., 1988	Questionnaire-based study 1121 United States of America	Reporting forms not available Event already documented Did not get to it/got busy Did not believe it was important Forms were too much trouble Minor or expected side effect Did not like interacting with the government Liability concerns Did not know how to report Undetermined as ADE Not primary physician		Age Time in direct patient care

Rowin et al., 2008 (82)	Descriptive study Sample size not stated United States of America		More likely to report no harm (nurses)  More likely to report permanent harm, near death, death and unsafe environment (doctors)  Type of incident: falls and medication (nurse)  Type of incident: adverse clinical event (doctors)	Temporary harm  Near miss
Sanghera et al., 2007 <sup>(83)</sup>	Semi-structured interviews 13 United Kingdom	Not being aware that an error had occurred  Detailed paperwork  Time constraints  Not understanding incident reporting process  No benefit (perception that nothing is done with the data)		

	1		1	<del>                                     </del>
		No encouragement by management Fear of loss of professional registration		
		Fear of being in trouble		
		Fear of looking incompetent		
		Feeling upset		
		Fear will be blamed		
		Not wanting to report colleagues' errors		
Sarvadikar et al., 2010 <sup>(84)</sup>	Questionnaire-based study 56 United Kingdom		Doctors more likely to report errors with worsening patient outcome	Nurses and pharmacists likely to report error regardless of patient outcome
Schectman et al., 2006 (85)	Questionnaire-based study 120 United States of America	Unsure of reporting mechanism  No actual harm came to the patient  Reporting too difficult and time	Allow electronic reporting of adverse events and near misses	
		consuming  Unsure of what is considered AE/NM	Clarify reporting mechanism	
		Unique di What is cullsidered AE/INIVI		

		Inadequate MD participation in scheme  Concern about consequences of reporting others' error  Reporting makes no difference (nothing will change)  Concern about being blamed or judged less competent  Weaknesses in the reporting system  Professional behaviours  Fear of retribution  Lack of feedback and the perception that change would not result from reports.	Clarify what constitutes an AE/NM  Allow anonymous reporting  Increase physician involvement in QI  Provide feedback on QI projects arising from reports  Provide individual feedback following report  Provide summary feedback on a regular basis  Make reporting mandatory
Schulmeister et al., 1999 <sup>(86)</sup>	Questionnaire-based study 160 United States of America	Minor error Fear of disciplinary action	
Sharma et al., 2008 <sup>(87)</sup>	Questionnaire-based study 81 United Kingdom	Does not achieve anything  Not in physicians culture	Anonymous system  Easily accessible

		Do not wish to incriminate others  Do not know how to access forms  Not bothered  Do not wish to ask nurse staff  Lack of time  Do not know which incidents need to be reported  Lack of anonymity  Not in habit of considering it  Discouraged by senior nurses	Forms not held by nursing staff
Soberberg et al., 2009 (88)	Questionnaire-based study 317 Sweden	I did not have enough time I am concerned about possible consequences Someone else did it It is too complicated No one else files incident reports It would not make any difference	

		Insufficient routines for reporting	
Soleimani., 2006	Questionnaire-based study 128	Threat of public outcry	
	New Zealand	Professional	
		consequences/discipline	
		Embarrassment in front of	
		colleagues	
Stratton et al.,	Questionnaire-based study	No positive feedback is given for	
2004 (90)	284	passing medications correctly	
	United States of America	Nurse administration focuses on the	
		person rather than looking at the	
		system	
		Too much emphasis is placed on	
		medication errors as a measure of the quality of care	
		Responses by nursing administration do not match the severity of the error	
		do not mater the seventy of the end	
		Individual/personal reasons  Nurses could be blamed if something	
		happened to the patient	
		Nurse believe other nurses will think	
		they are incompetent	

		Nurses fear adverse consequences from reporting  Patient might develop a negative attitude  Nurses fear reprimand from physician  Nurses fear losing their license  Nurses want to avoid potential publicity of medication errors in the media		
Sweis et al., 2000 (91)	Questionnaire-based study 280 United Kingdom	Legal liability  Fear of breaching patient confidentiality	Serious ADR rather than trivial  Rarely occurring ADR rather than common ADR  Confidence in recognising an ADR  ADR to an established drug rather than new drug  Active support of	Training in reporting  Gender  Type of hospital  Age

 	<u> </u>
	medical/pharmacy staff
	Written hospital policy for pharmacist ADR reporting
	Training and ADR meeting
	Increasing seniority
	Allocation of time for ADR monitoring
	Publicity and promotion by hospital and CSM
	Better cooperation with clinicians
	Support and encouragement by the pharmacy department
	More ward rounds and direct patient contact

			Simplify reporting system  ADR reporting team  Feedback
Tariq et al., 2012	Semi structured interviews 23 Australia	Lack of time	
Taylor et al., 2004	Questionnaire-based study 140 United States of America	Not important to report error that did not harm patient	Make reporting of errors mandatory
		Reporting errors does not make any difference	Different format for IR
		Unsure about what is considered medical	Use of electronic format for reports
		Incident report form too complicated	Reward for reporting medical errors
		Concerned about being blamed or judged incompetent	Better education about what is
		Concerned about implicating others  Unsure whose responsibility it is to	considered a medical error that should be reported
		report errors	Evidence that reporting of errors

Throckmorton et	Questionnaire-based study	Level of harm: no harm	led to system changes  Feedback on regular basis and frequencies of reported errors  Feedback regarding outcome of a specific error that has been reported  Level of harm
Throckmorton et al., 2007 <sup>(94)</sup>	Questionnaire-based study 435 United States of America	Level of harm: no harm	Working closely to the patient  Higher scores on the Wakefield's scale  Fewer years since initial license
Tobaiqy et al., 2013 <sup>(95)</sup>	Questionnaire-based study 61 Saudi Arabia	Lack of awareness  Workload/time constraints  Unavailability of reporting form	Continuing education events  An internet/web based reporting facility

		Reporting system complexity  Error too trivial  Lack of anonymity  Fear of blame  Concerns over penalisation  Difficulty in recognising errors	Training focused on error prevention  Anonymity of reporting  A non-punitive reporting culture  Financial incentives	
		Senior staff advised not to report  Lack of feedback from authority	linked to reporting	
Turner et al., (2013) (96)	Semi-structured interviews 32	Value-not convinced that the reporting system would deliver		
Uribe et al., 2002	United Kingdom  Questionnaire-based study	improvements in clinical care  Time involved in documenting an		Thinking that
(97)	122 United States of America	error		reporting has little
		Extra work involved in reporting  Hesitancy regarding 'telling' on		contribution for improvement of quality care
		somebody else		Not knowing
		Thinking that it is unnecessary to report error because it had no negative outcome		the usefulness of the report
				Lack of

Not being able to report	knowledge of
anonymously	what should be
	reported
Fear of lawsuits	
	Lack of
	recognition that
	a medical error
	has occurred
	Fear of being
	blamed
	Fear of
	disciplinary
	action/ losing
	job
	, , ,
	Lack of
	information in
	how to report
	Lack of interest
	or motivation
	for reporting
	Forms or
	computer
	locations not
	available to
	report medical
	errors

				Not knowing who is responsible for reporting error
Vessal et al., 2009	Questionnaire-based study 110 Iran	Uncertain association  Too trivial to report  Too well known to report  Yellow card not available  Not enough information from the patient  Not enough time  Unaware of the existence of a national ADR reporting system  Too bureaucratic  Did not know how to report  Fear of legal liability  Unaware of the need to report and ADR	The reaction is of a serious nature  The reaction is unusual  The reaction is to a new product  Reaction not reported before for a particular drug  Reaction is well recognised for a particular drug  Any reaction	
Vincent et al., 1998	Questionnaire-based study 198	Unnecessary		Unsupported colleagues

	United Kingdom	Increased workload Blame Worry litigation Busy/forgot		Not knowing which incidents to report  As long as staff learn from incident it is unnecessary to discuss/report  Fear disciplinary  Not wanting incident to be discussed  Who's responsibility  Little contribution
Vogus et al., 2007	Questionnaire-based study 1033	Safety organising	Trust in managers	Care pathways
	United States of America	Unit type (emergency)	RN experience	% of RNs with BSN
		Safety organising and trust	Unit type (IC)	Unit type
		Safety organising and pathways	Number of beds	(surgery)

		Patient-to-RN ratio		
Walji et al., 2011	Semi- structured interviews 12 Canada	Lack of knowledge about natural health products  Lack of time/priorities  Complexity of reporting process	Pharmacists who saw themselves as 'knowledge generators' rather than just 'knowledge users' were more likely to report and less likely to allow workplace challenges to prevent their taking an extra step	
Walker et al., 1998 (102)	Focus groups and questionnaire-based study 43 Australia	Minor incidents (documentation and minor variation from the prescription)  Negative past experience of reporting  Fear of getting into trouble  Fear they will somehow stand out from the crowd in the eyes of those in authority  Feelings of discomfort or uncertainty about being required to report an incident that involved a colleague	More likely to report an incident if patient safety compromised  Capacity to feedback and improve the situation  Reporting might help raise people's awareness of problems that could be occurring	Fear of possible punishment senior staff

This is more difficult if the colleague	
is a more experienced nurse	Wrong drug
Others expressed with view that they wouldn't report a friend, perhaps	Wrong route
perceiving that the friend would be in trouble if the incident was reported	Wrong person
Did not always want to admit their	Wrong dose
mistake	Harm to the patient
Might not even realise that an error had occurred	A desire to target an individual or
	professional group
Incident might be highly incriminating	to improve practice
If the patient actually came to harm as a result of the error	Legal obligation of the nurse to report
If the departure from the prescribed	
therapy seemed reasonable	
If the problem could be sorted out	
Concern about the time taken to fill in the incident report form	
Inadequate understanding of what constituted an error	
A lack of feedback on the number of medication errors was a problem	

		Perceived inaction on reported errors incidents	
Waring, 2004 <sup>(103)</sup>	Semi- structured interviews 37 United Kingdom	Acute medicine and rehab: IR system was regarded as nurse led, dealing with ward issues and the work of non-medical groups	
		Anaesthesia: Physicians remained sceptical about the hospital wide reporting system and were generally disinclined to participate in this approach	
Waring, 2005 (104)	Semi-structured interviews 28 United Kingdom	Fear of blame Blame culture	
		Peer of punishment	
		Fear of blame from pubic	
		Fear of litigation	
		Fear of professional competence being questioned	
		Fear of poor references	
		Reprimands from a senior colleague	

		Fear of use of reports-could be used at a later date in the event in medicolegal disputes		
Waters et al., 2012	Focus groups 16 Canada	Time Fatigue	Previous experience of litigation	Risk of litigation
		High workload  Relevance of reporting form	Protection against future litigation	
		Complexity of reporting-gathering many pieces of information.	Professional responsibility	
		Unit culture Fear of blame	IR perceived as learning opportunity	
		Close knit team	Desire for practice improvement	
		Other methods of reporting-verbal reporting and team debrief		
		Lack of feedback		
Weissman et al., 2005 (106)	Questionnaire-based study 203 United States of America	Mandatory  Non-confidential system	Serious harm	
		State run		

		Less harm	
Williams et al., 2013 (107)	Focus groups 17 United Kingdom	Severity (more likely to report if serious harm	Simpler reporting system  Targeted report  Feedback  Drug-specific error reporting forms  Electronic forms/systems (easier than paper)  Anonymous reporting
Winchester et al., 2012 (108)	Questionnaire-based study 120 United Kingdom	Concerned about confidentiality  Did not know the procedure for reporting  Did not think anything could be done  Did not feel incident was important enough to report  Believed source to be low risk  Reporting was inconvenient	Education  Adverts/posters  Training  Compulsory reporting  Simple reporting system  An electronic

			reporting system
Yong et al., 2003	Questionnaire-based study 136	Time constraints	Total anonymity and confidentiality
	New Zealand	Laziness and forgetfulness	, i
		Dislike form filling	Protection against punitive action
		A lot of work for little practical benefit	Simplify forms and bring up to date
		Forms too complicated	
		Do not believe the system is working	Easy access to forms
		Many incidents not worth reporting	Electronic data entry
		Many other tools exist for correcting	
		errors and improving standards	Incorporating IR form filling at
		Dislike the published interpretation of results with diagnostic views by	regular M&M meetings
		some anaesthetists	Mandatory
		Qualitative result not acceptable	
		Feel that the main benefit of IR is	Local analysis rather than
		local analysis and that very rare events distilled by multi-site	Australasian wide
		monitoring are less important	More aggressive follow up and
		Difficulty defining what constitutes incident	reviewing

		Inadequate feedback  Medico-legal implications  Forms not available/hard to locate  Lack of appropriate culture within department  Not accepted as part of private practice culture  Use of local IR system, hospital based audit  Incidents are discussed at department level confidentially	Publication of problems  Aims and purpose should be clarified explicitly  Select a few incidents to monitor frequency	
Zwart et al., 2011 (110)	Prospective cohort study 66 Netherlands		Expertise	Communicator Collaborator Manager Health advocate Scientist Professional

Adverse Drug Event (ADE); Adverse Drug Reaction (ADR); Adverse Event (AE); Australia and New Zealand College of Anesthetists (ANZCA); Bachelor of Science in Nursing (BSN); Critical Incident Reporting Service (CIRS); Drug related problems (DRP); Incident Reporting (IR); Iowa Department of Inspections Appeals (IDIA); Incident Information Management System (IIMS); Intensive Care (IC); Medication Administration Error (MAE); Medication and Healthcare Products Regulatory Agency (MHRA); Medical Doctor (MD); Morbidity and Mortality (M&M); Near Miss (NM); Patient Safety Culture (PSC); Quality Improvement (QI); Register Nurse (RN)

eTable 2: Frequency of factors influencing engagement in incident reporting

		Impact on Reporting Engagement		
Factor		Barrier Frequency Count (%)	Facilitator Frequency Count (%)	Negative Case (no impact) Frequency Count (%)
	Adverse consequences	51 (31.68%) (1, 2, 4, 11, 14, 17, 18, 20, 21, 23-25, 30, 35, 36, 43, 46, 47, 49, 51, 52, 55, 56, 62, 65, 69-71, 77, 79, 83, 85, 86, 88, 90, 95, 102, 104)	-	3 (25.00%) <sup>(16, 99, 102)</sup>
	Litigation	30 (18.63%) (4, 9, 10, 12, 13, 28, 35, 36, 40, 44, 46-49, 55, 56, 64, 66, 67, 69, 72, 74, 81, 91, 97-99, 102, 104, 109)	<b>8</b> (61.54%) <sup>(45</sup> , 47, 55, 56, 62, 66, 105)	4 (33.33%) <sup>(13, 39, 97, 105)</sup>
	Blame	<b>24</b> (14.91%) <sup>(3, 4, 17, 24, 30, 35, 36, 45, 46, 49, 52, 71, 78, 79, 83, 85, 90, 93, 95, 99, 104, 105)</sup>	4 (30.77%) (47, 49, 55, 66)	1 (8.33%) <sup>(97)</sup>
Fear of Adverse	Judgment	<b>22</b> (13.66%) <sup>(2, 10, 12, 13, 17, 21, 24, 41, 46, 47, 70, 73, 79, 83, 89, 90, 104)</sup>		1 (8.33%) (44)
Consequences	Relationships	12 (7.45%) (1, 2, 20, 24, 55, 77, 85, 89, 90, 93, 97, 104)	-	-
	Impact on career	10 (6.21%) <sup>(15, 24, 30, 55, 56, 72, 73, 83, 90, 104)</sup>	-	1 (8.33%) (50)
	Protection of self	7 (4.35%) <sup>(10, 12, 13, 42, 68, 80)</sup>	-	-
	Avoid discussion in meetings	4 (2.48%) <sup>(35, 49, 67, 109)</sup>	-	1 (8.33%) (99)
	Apprehension about sending inappropriate form	1 (0.62%) (43)	-	-
	Non-punitive	-	1 (7.69%) (109)	1 (8.33%) (8)
	Total	161 (100%)	13 (100%)	12 (100%)
Process and Systems of Reporting	Time	29 (26.36%) (9, 10, 17, 22-24, 27, 35, 44, 47, 49, 55, 56, 64, 67, 69, 71, 72, 79, 83, 87, 88, 95, 97, 98, 102, 105)	5 (6.67%) (37, 39, 55, 66)	-
	Complexity/simplification of reporting	<b>28</b> (25.45%) (10, 27, 29, 35, 44, 46, 47, 50, 55,	<b>15</b> <i>(20.00%)</i> <sup>(9,</sup> 11, 27, 44, 52, 55, 66,	1 (14.29%) (52)

		62, 64, 66, 69, 71, 72, 81, 83, 85, 88, 93, 95, 101, 105, 108, 109)	69, 91, 107-109)	
	Anonymity and/or confidentiality	22 (20.00%) (10, 12, 13, 35, 42, 44, 46, 49, 52, 55, 56, 68, 71, 87, 91, 95, 97, 106, 108)	16 (21.33%) (29, 39, 49, 52, 53, 55, 66, 69, 85, 87, 95, 107, 109)	1 (14.29%) [18]
	Reporting format	10 (9.09%) <sup>(29, 45, 69, 72, 85, 102, 105, 109)</sup>	21 (28.00%) (4, 10, 11, 30, 37, 43, 49, 52, 55, 66, 69, 78, 85, 93, 95, 107, 109)	3 (42.86%) (13)
	Type of reporting system	5 (4.55%) (24, 27, 106, 109)	11 (14.67%) <sup>(39,</sup> 44, 52, 62, 63, 85, 108, 109)	-
	Unknown destination of report	4 (3.64%) (10, 13, 44, 78)	-	-
	Not enough information to complete report	3 (2.73%)(10, 33, 98)	1 (1.33%) (42)	-
	Sharing/access of reports	3 (2.73%) (43, 49, 81)	-	-
	Insufficient routines for reporting	1 (0.91%) (88)	-	-
	Lack of reporting system	1 (0.91%) (20)	-	-
	Administrative task	1 (0.91%) (69)	-	1 (14.29%) (18)
	Relevant to different HCPs	1 (0.91%) (103)	2 (2.67%) (43, 66)	-
	Reporting focus	<b>1</b> (0.91%) <sup>(71)</sup>	2 (2.67%) <sup>(52)</sup>	-
	Information not readily available	1 (0.91%) (29)	-	-
	Not specified	-	-	1 <i>(14.</i> 29%) <sup>(18)</sup>
	When/where to report	-	<b>1</b> (1.33%) <sup>(109)</sup>	-
	Doesn't require input from doctors	-	1 (1.33%) (66)	-
	Total	110 (100%)	75 (100%)	7 (100%)
	Level of harm	40 (43.48%) (6, 12, 13, 21, 24, 28-30, 35, 46-49, 51, 54, 55, 64, 67, 69, 70, 73, 77-79, 81, 85, 86, 93-95, 97-99, 102, 106-108)	26 (47.27%) (6, 23, 29, 30, 32, 39, 43, 45, 47, 48, 50, 51, 55, 74, 91, 94, 98, 102, 106)	-
Incident Characteristics	Cause of incident	19 (20.65%) (6, 7, 9, 10, 28, 40, 44-46, 48, 54, 69, 74, 98, 102)	6 (10.91%) <sup>(6, 39, 42, 50, 91)</sup>	2 (100%) (50, 54)
	Frequency of incident	18 (19.57%) (6, 7, 23, 28, 29, 42-44, 48, 54, 57, 68, 69, 78, 81, 98)	13 (23.64%) <sup>(6,</sup> 23, 43, 55, 74, 91, 98)	-
	Type of incident	13 (14.13%) <sup>(9, 10, 23, 24, 35, 40, 62, 63, 67, 69, 72, 102, 109)</sup>	8 (14.55%) (23, 45, 102)	-

	Level of risk	2 (2.17%) (30, 55)	1 (1.82%) <sup>(30)</sup>	-
	Patient characteristics	-	1 (1.82%) (45)	-
	Total	92 (100%)	55 (100%)	2 (100%)
	Value/attitude towards reporting	53 (59.55%) (1, 4, 6, 9, 10, 15, 17, 21, 23, 24, 28, 35, 42, 44, 46-49, 52, 64-66, 69, 72, 78, 83, 85, 87, 88, 93, 96, 103, 108, 109)	<b>21</b> (51.22%) (10, 18, 19, 30, 32, 39, 45, 47, 50, 52, 55, 60, 66, 72, 105)	<b>12</b> (27.91%) <sup>(16, 25, 54, 77, 83, 97, 99)</sup>
	Forgetfulness	9 (10.11%) <sup>(7, 29,</sup> 35, 49, 54, 56, 72, 99, 109)	-	1 (2.33%) (54)
	Perception of self	9 (10.11%) (10, 12-14, 20, 49, 68)	2 (4.88%) <sup>(101,</sup>	6 (13.95%) (13, 110)
	Emotional response	6 (6.74%) (10, 12- 14, 20, 49, 68)	5 (12.20%) <sup>(29,</sup> 30, 69)	-
	Previous reporting behaviors	5 (5.62%) (3, 25, 40, 63, 87)	1 (2.44%) (53)	1 (2.33%) (54)
Individual HCP Characteristics	Exposure to errors	2 (2.25%) (18, 27)	1 (2.44%) (105)	-
	Length of time in employment	2 (2.25%) (25)	-	1 (2.33%) (25)
	Seniority	1 (1.12%)(25)	3 (7.32%) (57, 91, 100)	4 (9.30%) (25, 40, 50, 54)
	Data required for own purposes	1 (1.12%)(44)	-	-
	Work hours	1 (1.12%)(40)	1 (2.44%) (40)	1 (2.33%) (38)
	Demographics	-	2 (4.88%) (19, 25)	12 (27.91%) (16, 18, 25, 40, 50, 54, 81, 91, 100)
	Profession	-	5 (12.20%) <sup>(82,</sup>	5 (11.63%) <sup>(82, 84, 110)</sup>
	Total	89 (100%)	41 (100%)	43 (100%)
Knowledge and Skills	Clarify reporting mechanism	<b>36</b> (42.86%) <sup>(7, 10, 12, 13, 23, 27-29, 40, 42, 44, 46-49, 55, 56, 64, 66, 68, 69, 78, 81, 83, 85, 93, 98, 108)</sup>	2 (5.56%) (69, 85)	5 (33.33%) (53, 54, 97, 99)
	Adverse event/near miss clarity	31 (36.90%)(17, 23, 24, 29, 32, 45-47, 49, 55, 64, 66, 67, 69, 72, 79, 81, 85, 87, 93, 102, 109)	<b>7</b> (19.44%) <sup>(11,</sup> 49, 66, 69, 78, 85, 93)	2 (13.33%) (97, 99)
	Ability in error recognition	7 (8.33%) (17, 24, 43, 46, 74, 83, 95)	4 (11.11%) <sup>(42,</sup> 43, 74, 91)	1 (6.67%) <sup>(97)</sup>
	Training	5 (5.95%) (15, 18, 42, 45, 52)	21 (58.33%) (37, 42-44, 49, 62, 66, 68, 78, 95, 108, 109)	7 (46.67%) (15, 37, 54, 91)

	Awareness	4 (4.76%) (46, 79, 95, 98)	2 (5.56%) (43, 102)	-
	Not enough information about product being reported	1 (1.19%) (101)	-	-
	Total	84 (100%)	36 (100%)	15 (100%)
Work	Workload/priority	50 (62.50%) (1, 4, 7, 12-14, 22, 24, 28-30, 42, 43, 45-48, 50, 52, 54-56, 63, 65-69, 72, 78, 79, 81, 91, 92, 97, 99-101, 105, 109)	6 (33.33%) (29, 42, 43, 80, 91)	3 (30.00%) (8, 50, 81)
	Accessibility	27 (33.75%) (7, 10, 12, 13, 15, 23, 29, 40, 43-46, 56, 63-65, 68, 72, 81, 87, 95, 98, 109)	11 (61.11%) (11, 43, 44, 49, 52, 69, 87, 108, 109)	1 (10.00%) (97)
Environment	Not specified	2 (2.50%) (4, 64)	-	-
	Unit type	<b>1</b> (1.25%) <sup>(100)</sup>	<b>1</b> (5.56%) (100)	3 (30.00%) (75, 100)
	Physical working conditions	-	-	<b>1</b> (10.00%) <sup>(38)</sup>
	Satisfaction with work environment	-	-	1 (10.00%) (58)
	Care pathways	-	-	1 (10.00%) (100)
	Total	80 (100%)	18 (100%)	10 (100%)
Organization	Feedback/communication	26 (34.21%) (4, 5, 8, 15, 17, 24-26, 30, 35, 46, 49, 55, 65-67, 69, 71, 79, 85, 90, 95, 102, 105, 109)	29 (29.90%) (4, 10, 11, 42-44, 49, 52, 55, 61, 62, 66, 69, 75, 78, 85, 91, 93, 107, 109)	2 (9.09%) (37, 50)
	Reporting culture	17 (22.37%) (6, 8, 9, 15, 24, 46, 63, 66, 78, 88, 98, 100, 104, 105, 109)	16 (16.49%) (6, 16, 23, 31, 43, 53, 59, 60, 62, 69, 75, 80, 95)	1 (4.54%) (16)
	Learning/improvement	7 (9.21%) [20, 59, 76, 90, 94, 102, 103]	13 (13.40%) <sup>(4,</sup> 29, 39, 52, 59, 66, 69, 78, 102, 105)	2 (9.09%) (8,53)
	Use of data	7 (9.21%) (4, 17, 24, 79, 90)	2 (2.06%) (107, 109)	-
	Policy	6 (7.89%) <sup>(2, 43, 48, 52, 55, 71)</sup>	22 (22.68%) (9- 11, 30, 36, 39, 42-44, 49, 52, 53, 55, 62, 66, 91, 93, 95)	2 (9.09%) (37, 50)
	Management response	5 (6.58%) (14, 24, 52, 75, 83)	2 (2.06%) (30, 76)	4 (18.18%) <sup>(18, 53, 76)</sup>
	Outcomes of analysis	4 (5.26%) <sup>(47, 104, 109)</sup>	1 (1.03%) (69)	-
	Resource	2 (2.63%) (14, 52)	3 (3.09%) (37, 43, 68)	1 (4.54%) (37)
	Ownership	1 (1.32%) (39)	4 (4.12%) (37, 40, 50)	6 (27.27%) (37, 91)

	Hierarchy	1 (1.32%) (20)	-	-
	Size	-	3 (3.09%) <sup>(37, 38,</sup>	1 (4.54%) (38)
	Nursing quality	-	1 (1.03%) (18)	-
	Awareness	-	1 (1.03%) (69)	-
	Location	-	-	1 (4.54%) (38)
	Elapsed time of IRS integration	-	-	1 (4.54%) (37)
	Ward rounds	-	-	1 (4.54%) (37)
	Total	76 (100%)	97 (100%)	22 (100%)
	Relationships	13 (39.39%) (6, 14, 30, 36, 47, 49, 55, 56, 69, 87, 105)	2 (10.00%) <sup>(45,</sup>	-
	Influence of Seniors	7 (21.21%) (25, 45, 51, 59, 87, 95)	1 (5.00%) (49)	-
	Peer reporting	5 (15.15%) (28, 83, 102)	3 (15.00%) <sup>(18,</sup>	-
Team Factors	Teamwork/communication	3 (9.09%) (20, 43, 55)	<b>7</b> (35.00%) (31, 43, 80, 91)	2 (66.67%) (8)
	Support/encouragement	3 (9.09%) (35, 49, 69)	1 (5.00%) (49)	1 (33.33%) (99)
	Medical doctor involvement	1 (3.03%) (85)	1 (5.00%) (85)	-
	Error committed by junior staff	1 (3.03%) (30)	1 (5.00%) <sup>(51)</sup>	-
	Team culture	-	4 (20.00%) (10, 19, 60, 80)	-
Professional Ethics	Total	33 (100%)	20 (100%)	<b>3</b> (100%)
	Concealment	5 (21.74%) <sup>(1, 49,</sup>	1 (5.88%) (55)	-
	Duty	1 (4.35%) (9)	<b>8</b> (47.06%) (10, 32, 43, 44, 47, 102)	1 (25.00%) (50)
	Accountability	-	2 (11.76%)(23, 47)	-
	Responsibility	15 (65.22%) (2, 23, 33, 35, 40, 46, 48, 63, 66, 69, 72, 78, 85, 88)	5 (29.41%) (33, 34, 91, 105)	1 <i>(25.00%)</i> <sup>(38)</sup>
	Culture	2 (8.70%) (49, 87)	-	-
	Legal	-	1 (5.88%) (25)	2 (50.00%) (25)
	Total	23 (100%)	<b>17</b> (100%)	<b>4</b> (100%)

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