Risk management in dermatology: an analysis of data available from several British-based reporting systems

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Summary

Background The elimination or reduction of risk is a prime requirement of all healthcare workers. The matter has come to the fore in dermatological practice recently with the widespread use of effective drugs that have significant side-effects (e.g. retinoids, cytotoxic drugs, biologics), the increase in skin surgery, especially for skin cancer, and the extensive use of phototherapies.

Objectives To examine the available database from different agencies to which adverse events may be reported over at least a 5-year time frame, categorize the risks, look forward to where as yet unidentified risks might exist, and draw conclusions to improve the safety of dermatological practice. This work came about through a request from the National Patient Safety Agency [to the Joint Specialty Committee of the British Association of Dermatologists (BAD) and Royal College of Physicians] for information on risks to patients receiving treatment or investigation for skin disease.

Methods Organizations in the U.K. that receive information about adverse events, whether caused by drugs or procedures in dermatological treatments, were approached for information about reported events over a 5-year (or, in one case, 10-year) time frame up to 2009. Data were received from the National Patient Safety Agency, the Medicines and Healthcare Products Regulatory Agency, the National Health Service Litigation Authority, the Medical Protection Society and the Medical Defence Union. In addition, the results of a survey conducted in 2010 by the BAD of its members concerning potential critical incident reporting were included. The received information was analysed according to category of event and conclusions drawn about how best to manage the risks that were identified.

Results Adverse events were divided into the following categories, listed in order of the number of reports received: drug side-effects (biologics and retinoids), phototherapy dosage, drug monitoring (including initial screening), pregnancy prevention programmes, skin cancer follow-up (including acting on reports), dermatopathological reporting and conduct of dermatological surgery (including management of complications, equipment problems, use of lasers, cosmetic procedures and cryotherapy). Critical incidents reported by BAD members often concerned follow-up failures, e.g. of patients receiving systemic drugs or of those with skin cancer.

Conclusions Several of the reported adverse events concern systemic failures. Recommendations for risk reduction include the following points: better systems for drug monitoring (including regularity of attendance, provision of sufficient follow-up appointments, acting on results and adequacy of pregnancy prevention programmes); staff training and record keeping for phototherapy; acting on skin cancer multidisciplinary team meeting outcomes (including provision of sufficient follow-up appointments); and adequate training of staff in dermatological surgery including cryotherapy. Regular monitoring of the occurrence of such reports is needed to ensure safe practice and to identify early areas of new risk.
The reduction or elimination of risk to patients from treatments or investigations is a prime aim of all healthcare workers. Removal of all risk is not possible, even with the 'safest' and most familiar of drugs and procedures. Some risks, notably those of drugs or procedures with which there is a lot of experience, are well known, predictable and can be explained to patients. However, when it comes to newly introduced treatments or investigations, it is frequently not possible to forecast what all the risks may be even when clinical trials have been extensive and some of the potential problems have been revealed. One recent example of this is the problem of progressive multifocal leukoencephalopathy that only came to light after several years' clinical experience with the use of efalizumab in psoriasis but which led to the European Medicines Agency suspending the marketing authorization of the drug.1

Changes to service delivery models in the U.K. following the care closer to home agenda and initiatives such as choose and book may result in inadequate follow-up of patients with skin disease. These could result from the priorities that hospital and primary care trusts (PCTs) give to seeing new patients (due to financial penalties for not meeting targets, e.g. the 18-week target), the desire of PCTs to reduce hospital attendances wherever possible and the pressure put on trusts to increase new to follow-up ratios.

Systemic drugs are increasingly used in dermatological practice. Problems will arise if there is inadequate pretreatment screening or insufficient ongoing monitoring. This includes second-line agents for inflammatory skin disease such as methotrexate, azathioprine, mycophenolate mofetil, cyclophosphamide or ciclosporin. Female patients of childbearing age on the teratogenic drugs isotretinoin (given for severe acne) and altretinoin (used in hand dermatitis) will be at risk of malformations in babies.5 Patients with skin cancer may have increased morbidity and mortality if disease progression is not detected. Inadequate monitoring may result in failure to follow protocols, to perform the necessary tests or to look at and act on the results of tests.

The increasing use of new biologic agents for dermatologic diseases has attendant risks. These include ensuring that the use of the drug is appropriate, that pretreatment screening (e.g. for tuberculosis) and ongoing monitoring conform to national or local guidelines or those set out by the National Institute for Health and Clinical Excellence (NICE), and that the results of investigations and of any reported side-effects of the medication are acted on in a timely and diligent manner.3,4 Proper facilities are needed if biologics are going to be given by infusion, with specially trained nurses who can observe and treat infusion reactions. It is acknowledged that there may be as yet unknown, long-term side-effects from biologic drugs.

Pressures to provide dermatology management outside a hospital setting generate new risks. Providers must ensure that the local facilities, staff levels and training of attending staff are adequate for the type of procedure being undertaken. Management of collapse and haemorrhage in skin cancer surgical cases and management of anaphylaxis resulting from allergy testing must be equivalent in the community to that available in large hospital settings.

The new initiatives to improve skin cancer care in England require dermatologists to be trained and to record advice to patients on the diagnosis and future management of their skin cancer. Involvement of incorrectly trained medical or nursing staff who fail to follow the strict procedures may result in patients receiving substandard advice. Experience in the U.S.A. from 1990 indicates that injury litigation was experienced by a half of all respondents in residency programmes, and that this related to therapeutic or surgical complications in 50% of cases.5

Materials and methods

The Joint Specialty Committee on Dermatology was asked to advise the National Patient Safety Agency (NPSA) on where the risks lie in the treatment and investigation of patients with skin disease. Approaches to the assessment of risk can be prospective or retrospective. Prospectively, one can examine the patient journey and dissect out what may go wrong at each step. Retrospectively, it is possible to look at where problems have occurred in the past and decide if they could have been avoided.

The NPSA has a 'vision' to lead and contribute to improved, safer patient care by informing, supporting and influencing healthcare organizations and individuals working in the health sector.6

The appropriate persons at the National Health Service Litigation Authority (NHS LA), the Medical Defence Union (MDU), the Medical Protection Society (MPS), the NPSA and the Medicines and Healthcare Regulatory Authority (MHRA) were approached, in some cases using the Freedom of Information Act legislation, for information concerning reports of incidents involving the use of drugs prescribed by dermatologists (or their proxies), surgical procedures performed by dermatologists, or phototherapy given in departments of dermatology over a 5-year period. The requests were made at various times in 2009. Responses were obtained from all organizations.

The data from the NHSLA were requested and provided of successful litigation in the field of dermatology, dermatologic conditions and cryotherapy (specified) against NHS trusts in England over the 5 years to the end of November 2008. It is important to note that these reflect only the initial information given at the time of reporting and that many details that would subsequently come to light are not available from this database.

The MDU reported results over a 10-year period to March 2009, and the MPS over the 5-year period 2004–2008 inclusive.

The NPSA examined their National Reporting and Learning System (NRLS) from 1 January 2005 until 8 September 2009 for reports relating to methotrexate, azathioprine, mycophenolate mofetil, ciclosporin and ciclosporin reported from dermatologists, and for incidents relating to phototherapy.
The MHRA examined their reports between January 2005 and December 2009. The ‘yellow card’ scheme of the MHRA has characteristics that require comment before the data are examined. The reports concern suspected and not proven adverse drug reactions (ADRs). Reports are more frequent in the first 2 years of introduction of a new drug. Results cannot be used to infer frequency of reactions. ADRs were examined for biologics, retinoids, immunosuppressants (including ciclosporin, methotrexate, pimecrolimus, tacrolimus, azathioprine, mycophenolate mofetil, hydroxycarbamide) and for hydroxychloroquine and dapsone.

The MHRA medical device reporting data were obtained for the years 2005–2009 inclusive. All reports are assessed by MHRA experts who decide on whether and how the report should be investigated (e.g. by the MHRA, by the manufacturer or by a third party). Some of the reports may be more applicable to use of devices by plastic surgeons than by dermatologists (e.g. the use of dermatoes).

In addition, in order to obtain more of an opinion of the current state of play (rather than a retrospective as provided by the above reporting systems), brief details of a survey conducted by the British Association of Dermatologists (BAD) in the first half of 2010 were obtained (D.J. Eedy, honorary secretary BAD, personal communication 2010). In this survey, reports were invited from BAD members of potential critical incidents in dermatological practice: 100 responses were received from members.

Results

Retrospective information from the NHS Litigation Authority

A summary of the results in 98 cases are shown in Table 1. The biggest group of claims was related to dermatological surgery (44), followed by phototherapy (25), pathological reporting (15) and medical treatment or diagnosis (14). The largest single problem was administration of the wrong dose of phototherapy (24), followed by missed skin cancer on histopathological reporting (13), delay in diagnosis of skin cancer (13), inadequate excision of skin cancer or of surgical technique (seven), postoperative complications or inadequate postoperative care (six) and missed medical diagnosis (five).

Wrong side surgery or wrong lesion removal was a problem in three cases.

Retrospective information from the Medical Defence Union

The MDU reported that over a 10-year period to March 2009 there were 94 reported claims of which 33 were concluded without payment, six were settled, one was won, three were inactive and 51 remain active. There were 32 actual claims: six were settled, one was won, seven were active and 18 concluded (discontinued, statute barred or closed without payment). There were 62 potential claims of which 44 were active, three inactive and 15 concluded (discontinued, statute barred or closed without payment).

Of the six settled claims, five related to treatments on the face or head: two involved laser treatment, one damage from cryosurgery, one missed skin cancer, one wound infection and one nerve damage.

Of the 51 active cases, 10 relate to missed or delayed diagnosis, 10 to postprocedural complication (five involve treatment on the face, three involve scarring), three to treatment failure, two each to consent, wrong operation or performance concerns, and the others to various categories.

Retrospective information from the Medical Protection Society

Over the 5-year period 2004–2008, the MPS received 34 claims or preclaims and 14 complaints. Nineteen concerned laser treatments (e.g. for thread veins or hair removal) with blistering, pigment change and scarring as the main problems. Sixteen involved the use of Botox® (Allergan, Marlow, U.K.) or fillers, with swelling, bruising, unsatisfactory results and demands for reimbursement being the problems encountered. The remaining cases concerned scarring after cryotherapy or varicose vein injection.

Retrospective information from the National Patient Safety Agency National Reporting and Learning System database

The NPSA’s NRSL search revealed 63 incidents involving drug prescribing. Ten involved problems relating to monitoring and follow-up. These were usually system failures concerning blood monitoring, specifically missed clinic appointments, documentation errors, failure or delay in acting on or interpreting results, and sampling issues (e.g. lost or inadequate samples). The degree of harm was assessed as moderate for one, low for three and ‘no harm’ for six.

There were four incidents that related to lack of patient monitoring and follow-up of adverse reactions. In one case, a patient went for 7 weeks without review due to appointments being canceled and changed. In another a consultant expressed concern that ‘... patients no longer have the chance to be seen for follow-up appointments until a significant period of time [has elapsed]’ and in another, the problem related to the absence of hospital notes of a patient with a complex past history.

Twelve incidents concerning isotretinoin were examined and assessed by the NPSA as ‘low or no harm’. In one case, the contraceptive pill was not prescribed before the patient was due to start the drug. In another case, there was no local process for screening and in five cases there were incorrect or inconsistent results of pregnancy status or false positives. Four incidents relate to patient action. Specifically, a patient restarted isotretinoin from leftover stock without informing the general practitioner; a patient was not screened prior to starting the drug; a patient took isotretinoin from her
Table 1 Successful litigation in the field of dermatology, dermatological conditions and cryotherapy (specified) against NHS trusts in England over the 5 years to end November 2008, as recorded by the NHS Litigation Authority

<table>
<thead>
<tr>
<th>Procedure</th>
<th>n</th>
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<tbody>
<tr>
<td>Phototherapy</td>
<td></td>
</tr>
<tr>
<td>Wrong dose</td>
<td>24</td>
</tr>
<tr>
<td>Photoxic reaction</td>
<td>1</td>
</tr>
<tr>
<td>Dermatological surgery</td>
<td></td>
</tr>
<tr>
<td>Delayed diagnosis of skin cancer</td>
<td>11</td>
</tr>
<tr>
<td>Inadequate excision/technique</td>
<td>7</td>
</tr>
<tr>
<td>Inadequate postoperative care/complications</td>
<td>6</td>
</tr>
<tr>
<td>Laser problems</td>
<td>4</td>
</tr>
<tr>
<td>Wrong side/wrong lesion removal</td>
<td>3</td>
</tr>
<tr>
<td>Unnecessary surgery</td>
<td>3</td>
</tr>
<tr>
<td>Cryotherapy scarring</td>
<td>3</td>
</tr>
<tr>
<td>Poor cosmetic result</td>
<td>2</td>
</tr>
<tr>
<td>Delay in action/referring</td>
<td>2</td>
</tr>
<tr>
<td>Other</td>
<td>3</td>
</tr>
<tr>
<td>Pathology</td>
<td></td>
</tr>
<tr>
<td>Skin cancer under diagnosis</td>
<td>13</td>
</tr>
<tr>
<td>Skin cancer over diagnosis</td>
<td>2</td>
</tr>
<tr>
<td>Medical</td>
<td></td>
</tr>
<tr>
<td>Missed diagnosis</td>
<td>5</td>
</tr>
<tr>
<td>Side-effect after topical treatment</td>
<td>3</td>
</tr>
<tr>
<td>Rare drug side-effect not advised</td>
<td>2</td>
</tr>
<tr>
<td>Wrong drug prescribed</td>
<td>2</td>
</tr>
<tr>
<td>Failed to do drug monitoring</td>
<td>1</td>
</tr>
<tr>
<td>Use of nonsterile lancet for skin test</td>
<td>1</td>
</tr>
</tbody>
</table>

mother’s supply while awaiting an appointment; and lastly a patient stopped taking the contraceptive while on isotretinoin despite being informed of the risks of pregnancy and had a positive pregnancy test 3 months later.

Eight reports were received from dermatologists concerning biologic drugs and a further 13 reports may be related to treatment of skin disease (but the indication for use of the drug was not clear). All reports were classed as ‘low or no harm’. In 11 cases, limited clinical review due to missing or unavailable documentation led to omission or delay in treatment. In two cases, there was failure of follow-up on blood or other abnormalities prior to drug administration.

Three hundred and thirty-one reports were made to the NRLS about incidents involving phototherapy. Three were regarded as involving ‘serious harm’: in one case, burns from excessive treatment duration; in another, use of wrong device [i.e. ultraviolet (UV) B tubes instead of UVA]; and in another, calculation error or wrong dosing increments. Cases of poor documentation, treatment or wrong sites (or area not intended to be treated), and omission of use of protective garments, were noted.

Table 2 Spontaneous adverse drug reactions reported to the Medicines and Healthcare Regulatory Authority for the years 2005–2009. The indications for the dermatological drugs are either unknown or specified as a dermatological indication

<table>
<thead>
<tr>
<th>Procedure</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biologics</td>
<td>521</td>
<td>620</td>
<td>433</td>
<td>467</td>
<td>481</td>
</tr>
<tr>
<td>Immunosuppressants</td>
<td>248</td>
<td>216</td>
<td>121</td>
<td>153</td>
<td>186</td>
</tr>
<tr>
<td>Retinoids</td>
<td>116</td>
<td>95</td>
<td>95</td>
<td>91</td>
<td>92</td>
</tr>
<tr>
<td>Other</td>
<td>13</td>
<td>11</td>
<td>14</td>
<td>15</td>
<td>15</td>
</tr>
</tbody>
</table>

reports by year is as follows (note, this total cannot be obtained from adding up the figures in Table 2): 1894 in 2005, 1749 in 2006, 1935 in 2007, 1771 in 2008 and 1653 in 2009. The largest number of reports relates to biologic drugs. As far as possible, these reports (and those for immunosuppressive drugs) concern the use of these drugs for dermatological indications or where the indication is unknown. The figures for the retinoids are likely all to pertain to dermatological prescription as the drugs are used only for dermatological indications. The data provided by the MHRA do not give an indication of the type of ADR reported.

Retrospective Information from the Medicines and Healthcare Regulatory Authority medical device incident reporting

Over the 5-year period there were 18 reported incidents involving dermatomes or skin meshers: seven involved a problem with graft thickness, four with ‘jumping’ of blades, four with graft shedding, two with decontamination, one with malalignment of combs and one with loss of power. There were 15 incidents with phototherapy units. Ten incidents involved wrong or overexposure, four involved mechanical failures and one involved electrical failure. Four incidents specifically involved UVB – all concerned wrong or overexposure. Eleven incidents involved the use of lasers, all concerning wrong or overexposure. 10 were thought to result from either not following instructions or user error; one incident is still being investigated. Two incidents concern photodynamic therapy: in one case, the machine was wrongly calibrated; in the other, there was a manufacturing fault. One incident concerned use of liquid nitrogen. In this, liquid nitrogen was inadvertently sprayed onto the sole of the patient resulting in a large blister.

British Association of Dermatologists’ survey of potential critical incident reporting

Of the 100 responses, 52 were from teaching hospitals and 44 from district general hospitals (D.J. Eddy, honorary secretary BAD, personal communication 2010). Seventy per cent of departments regularly completed potential critical incident (PCI) forms, filled in by doctors in 70% of cases.

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Fifty responders (i.e. 50%) felt there had been an increase in PCIs over the previous 5 years as a result of NHS reforms (although 30 felt there had been no such increase). The biggest increase in reportable PCIs was in the failure to follow up patients receiving systemic (e.g. cytotoxic) drugs (54%), followed by failure to follow up patients with skin cancer (34%), followed by PCIs involving less-well-trained staff, e.g. in phototherapy (32%). Concerning feedback, 55% felt they received none from their NHS trust on reported PCIs.

Discussion

Surprisingly little has been published on where risks lie in the field of dermatological practice, aside from the side-effects, many of which are well recognized and included in reports of clinical trials of drugs. Drummond et al. describe the experience in the Scottish NHS over a 12-year period (1989–2001). They found 30 claims, most in five main areas: phototherapy (eight cases), therapy/treatment (eight), cryotherapy (six), surgery (four) and misdiagnosis (three), and also an injury after fainting (one case). All the phototherapy claims involved burns from overexposure to UV radiation. Two therapeutic claims involved overdose with methotrexate. In the U.S.A., 50% of all claims in dermatology relate to surgery or therapeutic complications.5

The main risk areas to patients in dermatological practice gleaned from data of the NPSA are over-dosing in phototherapy, the delayed diagnosis of skin cancer, the conduct and complications of skin surgery, the under-reporting of malignancy in dermatopathology, the missed diagnosis of serious inflammatory dermatoses and problems from drug side-effects. The areas of risk broadly reflect the findings of the Scottish study of the 1990s, but there were more claims made in the area of skin surgery and pathology. This may reflect a change in dermatological practice, with skin surgery being a more prominent part of dermatology in the present day and an increase in the frequency and importance of skin cancer. The problem of phototherapy overdose can be addressed through compulsory high-quality training of nursing staff or physiotherapists who administer the UV radiation, adequate staffing levels of phototherapy units and meticulous record keeping.

The data from the MDU and MPS relate mostly to private dermatological practice. They reveal that the main areas of concern in this field of practice are missed or delayed diagnosis and postprocedural complications. The latter especially relate to treatment on the head or face, the use of lasers or to cosmetic procedures, such as the use of Botox® or fillers. Many of these issues can be addressed via local and national guidelines. The conduct of skin surgery and the management of complications may be improved by compulsory high-quality training and audit for medical and nursing staff in primary and secondary care in keeping with NICE guidelines, with audit of record keeping. Policies should include measures to prevent 'wrong site' or wrong lesion surgery.

General dermatopathology reporting, even by general pathologists, has a low rate of error as judged by blinded review.8 However, a study of surgical and cytological malpractice claims showed that 46 of 362 involved misdiagnosis of malignant melanoma, and of these 32 were false-negative diagnoses.9 Even among experienced pathologists there is variation in opinion for melanocytic lesions, especially when considering in situ malignant melanoma.10 In order to address the issues of inaccuracy in dermatopathology accurate reporting, mechanisms have already been introduced by pathologists, e.g. double-reporting of skin cancer cases and peer-review audit. Multidisciplinary teams and peer-review systems should ensure that the histopathological results of skin biopsies are communicated to patients and any further treatment is organized. For clinical dermatologists, the mis- or missed diagnosis of malignant melanoma is also associated with a high risk of malpractice claims.11 The requirement of all dermatologists to be appraised and the proposed introduction of competency assessment should ensure sufficient expertise.

The Harvard Medical Practice Study found that adverse events occurred in 37% of hospitalizations, of which 27.6% were due to negligence.12 There is evidence that voluntary schemes for the reporting of ADRs identify only a small fraction of the adverse drug events that actually occur.13 Indeed, errors in writing up medication at least for inpatients, are known to be common, being found in 6% in one series (based in a children’s unit), with the errors resulting in actual adverse reactions in 0.24% and potential adverse reactions in 1%.14 Often the potential for adverse reactions to drugs is well recognized, e.g. to minocycline,15 as are the consequences of the immunosuppressive or other mechanisms of action of drugs such as the biologic agents.16

The reporting of ADRs is reasonably well organized in western countries such as the U.K. (where reports may be made to one or more agencies) and there are schemes in other countries such as the U.S.A.17 However, all schemes suffer from the problem of under-reporting. An additional problem, as exemplified by the example of eflornithine, is that a serious but relatively infrequent side-effect may be revealed only in the postmarketing phase when hundreds or thousands of patients have received the medication. Schemes to control closely known potential side-effects of drugs, such as teratogenicity associated with retinoids, are now well established especially for retinoids, e.g. isotretinoin or altretinoin, which may be used in women of childbearing potential.18

In assessing clinical incidents, it is important not to confuse the actual harm caused by that particular occurrence with the potential harm (future risk assessment) that also forms part of the incident reporting process. There should be no scope for downgrading the actual harm suffered by the patient as these criteria are defined in the U.K. by the NPSA and the criteria are clearly indicated on their online reporting forms which are the basis for incident reporting. The future risk assessment, on the other hand, is a frequent

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cause for misunderstanding. This assessment comprises two elements: the likelihood that the problem will recur and the most likely outcome in case of a recurrence (R.N. Satham, personal communication 2010). It is possible that in the most extreme case some adverse events could have a fatal outcome but in reality this is likely to be rare. If the most frequent outcome for that event would be no harm or minor harm then this incident would be graded according to the most frequent outcome and the frequency score would reflect this likelihood. For example if the event is expected to occur at least annually then the likelihood score would be 2 out of a possible 5, if the event’s most likely outcome were minor harm then this too would score only 2 out of 5, giving an overall risk rating of 4/15. This area is poorly understood by clinicians and can result in a belief that incidents are being downgraded.

The survey of members of the BAD showed that areas of concern in British dermatology at present are the adequacy of provision for follow-up of (i) patients on systemic therapies (in order to ensure safe prescribing and detect any side-effects early) and (ii) patients who have had a skin cancer (to detect early any recurrence or a new cancer). There is a potential danger that vital follow-up activity may be displaced with potentially damaging consequences, in view of the fact that the current ‘target-based culture’ places emphasis on meeting new patient targets. Targeting new patient referral times and changes to models of service delivery following the care closer to home agenda and initiatives such as choose and book may limit the capacity for safe monitoring. Limited priority for follow-up of patients on second-line agents for inflammatory skin disease, biologic agents for psoriasis, isotretinoin for acne and those being followed up for skin cancer may result in missed iatrogenic illness and disease progression. The solution is to ensure that certain categories of follow-up patients are given adequate priority. Additionally, the use of protocols and pro formas for drug monitoring and the setting up of specific nurse-led drug monitoring clinics is suggested to ensure safe drug use and early detection of side-effects. This is especially important for biologic agents and one positive development in this area is the foundation of the BAD Biologic Interventions Register (BADBIR), based at the University of Manchester (http://www.badbirc.org/index.asp). This is an epidemiological prospective observational cohort study comparing patients receiving biologic therapy with those receiving conventional therapy, designed to detect unforeseen side-effects of these drugs.

In conclusion, risk management in dermatology is an area that will develop further over the forthcoming years as hospitals become more aware of the need to control, record and monitor risk. To address the problem of managing risk in dermatology, it is important to ensure that adequate standards are upheld with regard to facilities, staff training and vigilance in practice, working to protocols and record keeping when undertaking phototherapy.

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What's already known about this topic?

- In dermatological practice there is increasing use of effective drugs that have significant side-effects (e.g. retinoids, cytotoxic drugs, biologics), increasing practice of skin surgery especially for skin cancer, and extensive use of phototherapies.
- There have been few attempts to assess the risks but indeed the brief literature shows that the main problem areas are in phototherapy, skin surgery and medical misdiagnosis.

What does this study add?

- Adverse events reported to different U.K. agencies over at least a 5-year time frame were assessed according to category.
- In order of the number of reports received problems were identified as: drug side-effects, phototherapy dosage, drug monitoring, pregnancy prevention programmes, skin cancer follow-up, dermatopathological reporting, conduct of dermatological surgery, use of lasers, cosmetic procedures and cryotherapy.
- Recommendations for risk reduction include better systems for drug monitoring, acting on results, adequacy of pregnancy prevention programme provision, staff training and record keeping for phototherapy, acting on skin cancer multidisciplinary team meeting outcomes, and adequate training of staff in dermatological surgery including cryotherapy.
- Regular monitoring of the occurrence of such reports is recommended to ensure safe practice and to identify early areas of new risk.

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References