**Difficulty in eye drop administration for people with rheumatoid arthritis**

Abstract:

Introduction

Many people require eye drops administered daily, yet many don’t instil them as prescribed. This can be due to physical difficulty managing the delivery device yet little research has focused on this.

Methods

Participants from ophthalmology and rheumatology clinics at hospitals within 2 regions in Scotland (n= 206) were recruited and asked to complete a questionnaire about eye drop use and difficulties they experienced. Binary logistic regression was used to assess the independent relationship between key explanatory variables and the major outcome variable which was difficulty in administration.

Findings

It was found that 62 per cent of people who attended an RA clinic reported difficulty instilling eye drops and that they were four and a half times more likely to have difficulty than people who attended an ophthalmology clinic. A greater proportion of women and younger people attended the RA clinics than the ophthalmology clinics, however, the reasons given for having difficulty and the level of adherence did not differ between the two groups.

Conclusion

The number of people newly diagnosed with RA is increasing worldwide, particularly among women, and many need eye drops. Experiencing difficulty instilling them is therefore a significant international health issue.

Introduction:

Concerns that patients do not administer eye drop medication as prescribed have been investigated repeatedly, however few studies have focused on whether the patient can use the delivery system correctly (Robin, 2010) ). A number of recent studies have reported the difficulties experienced by people who are required to self-administer eye drops on a regular basis (Kerr et al., 2013; Gupta et al., 2012) and research has focused predominantly on ophthalmology patients who have glaucoma (Budenz, 2009).People with Rheumatoid Arthritis (RA) are particularly predisposed to dry eye syndrome (Foulks, 2008) which can cause severe discomfort and affect their quality of life (Moss et al., 2004). For example, people with dry eye syndrome have reported that the symptoms prevent them from reading, watching television and using a computer (Miljanović et al., 2007). In order to manage the troubling symptoms people frequently instil eye drops as often as four times a day (Friedman, 2010). However, reduced fine motor capability can make the process of squeezing the eye drop dispensing bottle difficult, if not impossible (Wolfe and Michaud, 2008).

Literature

Literature regarding eye drop administration was accessed using Medline, CINAHL, EM-Base, Cochrane, and the Johanna Briggs Institute. The search was limited to papers written in English and no date limitation was applied. Keywords entered included glaucoma, dry eye syndrome, sjogrens syndrome, keratoconjunctivitis sicca, ophthalmic solutions, eye drop, eye medication, administration topical, medication adherence, compliance, non-adherence, arthritis rheumatoid.

To date there has been only one published research article that has focused on this patient group and eye drop administration. (Averns et al., 1999). Averns, Hall, and Webley found that 37 per cent of people with RA who were undergoing outpatient follow-up had had symptoms of dry eye syndrome for at least three months at some time and 25 per cent were currently symptomatic. It was evident that many patients had difficulty using eye drops due to problems aiming and squeezing the bottle (Averns et al., 1999). In an assessment of 30 people with current symptoms, the authors found that an Opticare device improved the ability to squeeze out drops and get them in the eye (Averns et al., 1999).

While the prevalence of RA is not extremely high (1-2% of the population), these people are a sizeable population group worldwide (Arthritis Research UK; Australian Government, 2009) and are often referred to occupational therapists for assessment and support . Given that a substantial number of people with normal joint functioning and reasonable dexterity experience difficulty in handling and squeezing eye drop containers (Gupta et al., 2012), it is very likely that correct eye drop administration for people with RA who have muscle weakness is problematic. This is a significant issue, because dry eye syndrome causes a great deal of discomfort (Le et al., 2012), and when it goes untreated it is likely to further increase the burden of RA and negatively influence the quality of life experienced by those affected.

People with RA who experience dry eye syndrome were recruited into this study. The primary aim was to determine the prevalence of difficulty in eye drop administration and to compare and contrast their experience with that of people who attend an eye clinic for conditions such as glaucoma. The secondary aim was to examine the relationship between participant and treatment characteristics and difficulty in administering eye drops.

Methods

Setting and sample

This cross-sectional study recruited participants from patients attending ophthalmology and rheumatology clinics at major public health facilities within 2 regions in Scotland. In Region 1 (total population≈800,000), during July and August 2012 a total of 11556 patients were seen at the ophthalmology clinic (mean=5778 per month) and a total of 2135 patients were seen at the rheumatology clinic (mean=1,067 per month). In Region 2 (total population≈359,000), In Region 2 (total population≈359,000), in July and August 2012 at total of 4349 (mean=2175 per month) patients were seen at the ophthalmology clinic and a total of 973 (mean=485 per month) patients were seen at the rheumatology clinic.

Summer and autumn months were chosen for data collection to avoid poor attendance due to adverse weather conditions. Twenty-three clinics were identified across the two regions (Region one: Ophthalmology [n= 5], Rheumatology [n=6]; Region two: Ophthalmology [n=8], Rheumatology [n=4]). Each clinic was scheduled to last for up to three hours depending on the number of appointments made. All adults who were prescribed eye drops and could speak and understand English were considered eligible for inclusion in the study. The numbers of people attending at each rheumatology clinic was smaller, and the proportion of eligible people also less, than those attending at each ophthalmology clinic. Of the 223 people who were eligible, only 17 declined to participate. The reasons given for non-participation included: in a hurry (n= 3), communication problems (n=2) and don’t want to participate (n= 12).

Procedure

Specialist nurses and clinical managers were contacted in each centre to identify which clinics would be best suited to recruit participants based on number of consultants working and number of patients booked. The medical staff were also consulted and permission was granted to speak with their patients. Participants were recruited by experienced research nurses while they waited for their consultation at the ophthalmology or rheumatology clinics. Every person who met the inclusion criteria and was present in the waiting room was approached. Informed, written consent was obtained and the person was asked to complete the questionnaire and return it to the research nurse. The research nurses made themselves available to read questions and complete the questionnaire for any patient who had difficulty due to impaired vision or poor writing. A very small number of patients indicated that they would prefer to take the questionnaire home to complete it. They were issued with a stamped addressed envelope and asked to post it to the researchers after completion.

The study was approved by the Edinburgh Napier University Ethics Committee and the South East Scotland Research Ethics Service.

Instrument

Validated questionnaires about eye drops use were considered (Bechetoille et al., 2008; Kholdebarin et al., 2008; Nordmann et al., 2007) but found not to focus on the factors of particular interest in this study. Therefore, a questionnaire was developed specifically for this purpose. The questionnaire design was informed by: previous research; speaking with people who use eye drops across a range of ages; feedback from an expert panel consisting of 2 consultant ophthalmologists, 2 ophthalmology nurse specialists; 2 hospital pharmacists who dispensed eye drops; and 2 research nurses. Content and face validity was established through consultation with the expert panel. The questionnaire was piloted with ophthalmology and rheumatoid arthritis patients and revised to improve specificity, readability and response burden prior to implementation.

The questionnaire consisted of 22 questions which assessed: demographic characteristics (Stryker et al., 2010); awareness of what condition was being treated and knowledge of the disease (Cook et al., 2010); frequency of eye drop use; adherence to the prescribed dose and reasons for not doing so (Kass et al., 1986); number of eye drop types prescribed; duration of eye drop use (Balkrishnan et al., 2003); difficulty in administering eye drops and reasons why (MacLaughlin et al., 2005); satisfaction with eye drop dispenser(Regnault et al., 2010); information sources about administration technique and helpfulness of instruction (Sleath et al., 2008); confidence in administering medication(Nordmann et al., 2007); assistance with the administration of eye drops; the use of, and satisfaction with, administration aids(Kahook, 2007).

Statistical analysis

With the effective sample size the study had over 80 per cent power to detect a 60 per cent difference in prevalence of difficulty in administering eye drops between ophthalmology and rheumatology patients with a 5 per cent probability of incorrectly rejecting the null hypothesis that there was no difference. Following data entry all variables were surveyed for incorrect codes and appropriate corrections were made. All missing data were left as missing. The prevalence of all variables were calculated for ophthalmology clinic attenders and RA clinic attenders, and compared using chi-square. Odds ratios were calculated to assess the bivariate relationship between key explanatory variables (gender, age, clinic type, service provider, years of treatment, the provision of professional instruction, and level of confidence in administering drops) and the major outcome variable (difficulty in self-administering eye drops). Binary logistic regression was then performed to assess the independent relationship between key explanatory variables and the major outcome variable. Statistical significance was set at a minimum of *p* < .05. Statistical analysis was conducted using SPSS software.

**Results**

Over a period of three months 206 out of 223 (92.4%) people who were asked to participate completed the study questionnaire. The prevalence of participant demographics, condition, and eye drop use is presented in Table 1.

**Table 1.**: **Prevalence of participant demographics, condition, and eye drop use**

|  |  |  |
| --- | --- | --- |
| **Characteristic** | **Ophthalmology**  **% (number)** | **Rheumatoid**  **Arthritis**  **% (number)** |
| Gender  Male  Female  Age  31-60 years  61-90 years  Service provider  Region 1  Region 2  Condition  Glaucoma  Dry eye syndrome  Glaucoma and Dry Eye  Other condition  Years of treatment  Up to 5 years  6 years or more  Frequency of eye drop administration  Once or twice per day  3 times per day or more  Number of different medications  One  Two  More than two  Help from a family member or friend  Yes  No  Confidence with self administering drops  Very confident  A little confident  Not confident | 41 (63)  59 (92)  21 (33)  79 (125)  65 (104)  35 (55)  61 (94)  24 (36)  8 (12)  7 (11)  66 (104)  34 (53)  66 (105)  34 (54)  49 (76)  38 (60)  13 (20)  25 (39)  75 (120)  80 (125)  16 (25)  4 (7) | 15 (7)  85 (40)\*\*  48 (22)  52 (24)\*\*\*  83 (39)  17 (8)\*  20 (9)  73 (32)  0 (0)  7 (3)\*\*\*  63 (29)  37 (17)  72 (33)  28 (13)  55 (26)  34 (16)  11 (5)  26 (12)  74 (34)  75 (34)  16 (7)  9 (4) |

Chi-square difference in prevalence: \* p-value < .05, \*\* p-value < .01, \*\*\* p-value < .001

Table 1 shows that 59 per cent of those who were attending the ophthalmology clinic were female compared with 85 per cent who were attending the RA clinic (*p* < .01). Age also differed between the two groups with 48 per cent of RA clinic attenders aged between 31 and 60 years compared with 21 per cent of ophthalmology clinic attenders (*p* < .001). Most RA clinic attenders were recruited from region one (83%) as were ophthalmology clinic attenders (65%) (*p* < .05). While the great majority (73%) of RA clinic attenders had dry eye syndrome, 20 per cent had glaucoma , and seven per cent had some other condition. The prevalence of conditions reported by ophthalmology clinic attenders was somewhat different (*p* < .001) with 61 per cent having glaucoma, 24 per cent dry eye syndrome, eight per cent having glaucoma and dry eye syndrome, and seven per cent having some other condition. Years of treatment, frequency of eye drop administration, number of different medications, help from a family member or friend and confidence with self-administering drops were not significantly different between the two groups. While nine per cent of RA clinic attenders compared with four per cent of ophthalmology clinic attenders reported that they were not confident with self-administering drops this difference was not statistically significant at *p* < .05.

The prevalence of difficulty and adherence in using drops is presented in Table 2. Table 2 shows that twice as many RA clinic attenders as ophthalmology clinic attenders reported experiencing difficulty administering eye drops (62% versus 31%) (*p* < .001). The type of bottle or dispenser (41%), taking the lid off (24%), squeezing the bottle (33%), missing the eye (43%), getting the correct number of drops in (22%), and fear of touching the eye (26%) were the most common reasons given by ophthalmology clinic attenders for having difficulty. Timing of when to put the drops in (21%), taking the lid off (21%), squeezing the bottle (48%), missing the eye (55%), and handling the bottle (28%) were the most common reasons given by RA clinic attenders for having difficulty. The number of reasons reported for having a difficulty was not significantly different between the two groups. Table 2 also shows that 28 per cent of ophthalmology clinic attenders and 32 per cent of RA clinic attenders did not always put their drops in according to prescription. The most common reason for non-adherence was simply forgetting and missing a dose (71% and 93% respectively). The number of reasons given for non-adherence were similar for both ophthalmology and RA clinic attenders (one or two reasons = 91% and 93% respectively).

**Table 2.**: **Prevalence of difficulty and adherence in using drops**

|  |  |  |
| --- | --- | --- |
| **Characteristic** | **Ophthalmology**  **% (number)** | **Rheumatoid**  **Arthritis % (number)** |
| **Difficulty**  Participant has difficulty self-administering eye drops  No  Yes  Reasons given for having a difficulty  Timing of when to put them in  Number of different bottles  Type of bottle or dispenser  Taking the lid off  Holding the bottle or dispenser  Squeezing the bottle  Keeping hands steady  Position the head  Missing the eye  Getting the correct number of drops in  Handling the bottle  Fear of touching the eye with bottle or dispenser  Drop stings the eye  Number of reasons given for having a difficulty  One  Two  Three  Four or more  **Adherence**  Participant puts drops in according to prescription  Yes  No  Reasons given for non-adherence  Forgot and missed a dose  Drop stings the eye  Drop causes blurred vision  Forgot and administered a second drop  Don’t like doing it  Can’t explain  Number of reasons given for non-adherence  One  Two  Three | 69 (110)  31 (49)  2 (1)  2 (1)  41 (21)  24 (12)  10 (5)  33 (17)  4 (2)  14 (7)  43 (22)  22 (11)  14 (7)  26 (13)  4 (2)  33 (17)  26 (13)  22 (11)  19 (10)  72 (115)  28 (44)  71 (31)  7 (3)  9 (4)  18 (8)  0 (0)  5 (2)  73 (32)  18 (8)  9 (4) | 38 (18)  62 (29)\*\*\*  21 (6)\*\*  10 (3)  17 (5)\*  21 (6)  7 (2)  48 (14)  10 (3)  14 (4)  55 (16)  14 (4)  28 (8)  10 (3)  7 (2)  35 (10)  24 (7)  7 (2)  34 (10)  68 (32)  32 (15)  93 (14)  0 (0)  7 (1)  7 (1)  13 (2)\*  0 (0)  66 (10)  27 (4)  7 (1) |

Chi-square difference in prevalence: \* p-value < .05, \*\* p-value < .01, \*\*\* p-value < .001

The prevalence and source of professional instruction and use of an eye drop administration aid were also compared between ophthalmology and RA clinic attenders. A slightly higher proportion of ophthalmology clinic attenders had received professional instruction in the administration of eye drops (56%) compared with RA clinic attenders (42%). For most participants the instruction was given by a nurse (67% and 53% respectively) or a doctor (23% and 21% respectively). Most participants who had received instruction reported that it was very helpful or quite helpful (98% and 94% respectively). Only eight per cent of ophthalmology and seven per cent of RA clinic attenders had ever been offered an eye drop administration aid. Of the ophthalmology clinic attenders 40 per cent reported that the aid was not helpful and 80 per cent said they were dissatisfied or very dissatisfied with it. For RA clinic attenders 33 per cent reported that the aid was not helpful while 100 per cent were either dissatisfied or very dissatisfied.

The unadjusted and adjusted relationship between key explanatory variables and the major outcome, difficulty in administering eye drops, is presented in Table 3. Table 3 shows that in unadjusted analysis, female gender (OR 1.90; *p* < .05), being a RA clinic attender (OR 3.62; *p* < .001), having six or more years of treatment (OR 2.09; *p* < .05), and having little (OR 2.40; *p* < .05) or no confidence (OR 9.53; *p* < .01) were all associated with report of difficulty in self-administering eye drops. Neither age, service provider, nor having professional instruction were associated with having difficulty. In adjusted analysis, having little (OR 2.73; *p* < .05) or no confidence (OR 25.8; *p* < .01) was again associated with report of difficulty. Other than having no confidence the strongest association was found between the type of clinic attended. Those who attended a RA clinic were four and a half times more likely than those who attended an ophthalmology clinic to report having difficulty in self-administering eye drops (OR 4.48; *p* < .001). Number of years treatment was also strongly related to difficulty, with those who have been treated for six or more years over three times more likely to report having a problem (OR 3.29; *p* < .001). Neither gender, age, service provider, nor having professional instruction were associated with having difficulty in adjusted analysis.

**Table 3: Relationship between participant and treatment characteristics and difficulty in administering eye drops**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Characteristic** |  |  | **Difficulty**  **Unadjusted**  **analysis** | **Difficulty**  **Adjusted**  **analysis** |
| Gender  Male  Female  Age  31-60 years  61-90 years  Clinic  Ophthalmology  Rheumatology  Service provider  Region 1  Region 2  Years of treatment  Up to 5 years  6 years or more  Professional instruction ever provided  Yes  No  Confidence with self administering drops  Very confident  A little confident  Not confident |  |  | 1.90 (1.02-3.54)\*  0.90 (0.48- 1.70)  3.62 (1.84-7.12)\*\*\*  0.75 (0.41-1.41)  2.09 (1.16-3.79)\*  1.11 (0.63-1.96)  2.40 (1.11-5.18)\*  9.53 (1.99-45.7)\*\* | 1.87 (0.91-3.86)  1.55 (0.71-3.41)  4.48 (1.92-10.5)\*\*\*  0.98 (0.47-2.05)  3.29 (1.65-6.55)\*\*\*  1.20 (0.61-2.36)  2.73 (1.15-6.49)\*  25.8 (2.95-225.3)\*\* |

\* p-value < .05, \*\* p-value < .01, \*\*\* p-value < .001

**Discussion**

The aim of this study was to estimate the prevalence of difficulty experienced in eye drop administration by people who have RA and to compare this with the prevalence of difficulty experienced by people who administer drops for eye conditions, such as glaucoma. We found that 62 per cent of people who attended an RA clinic reported having difficulty instilling their eye drops and that they were four and a half times more likely to have difficulty than people who attended an ophthalmology clinic. We also found that a significantly greater proportion of women and younger people attended the RA clinics than the ophthalmology clinics, however, the reasons given for having difficulty and the level of adherence did not differ between the two clinic groups. As to the relationship between participant and treatment characteristics and difficulty in administering eye drops, we found that, other than the type of clinic attended, the only other factors associated with difficulty were six or more years of treatment and a low level of confidence reported in administering drops. While women were more likely than men to have difficulty in unadjusted analysis, neither female gender, old age, or a lack of professional instruction in administering drops were associated with difficulty in administering drops in adjusted analysis.

To our knowledge, the prevalence of difficulty experienced by people with RA in administering eye drops has not been reported previously. In the only published research that has focused on eye drop administration by people with RA, Averns and associates stated that many people had problems (Averns et al., 1999). Given this previous research, anecdotal evidence, and an understanding of the mechanics of squeezing an eye dropper container, the high proportion of 62 per cent of people with RA experiencing difficulty in this study is unlikely to be an over-estimate. It does concur with one other study (Hennessy et al., 2010) that found that applying the correct number of drops is an issue for over 50 per cent of people who have arthritis. Conversely, Kerr and associates (Kerr et al., 2013) surveyed people diagnosed with glaucoma to explore satisfaction with ocular medicines and found that co-morbidities such as arthritis did not predict difficulty instilling eye drops.

The finding that people attending a rheumatology clinic were four and a half times more likely than people attending an ophthalmology clinic to experience difficulty administering eye drops is another result that has not been previously reported. In this study, 31 per cent of people attending an ophthalmology clinic reported difficulty putting eye drops in.

Although only one previous study has focused on people with RA and eye drop administration (Averns et al., 1999) it is well known that successful, accurate administration requires manual dexterity, eye hand coordination and good vision (Moore et al., 2014). This task, therefore, poses particular challenges for people with RA in terms of sufficient strength and dexterity to handle and squeeze the bottle which is a vital to administration of eye drops with the current delivery system. Observation of people instilling eye drops has demonstrated that as they reach the limit of their capability to exert pressure on the bottle they are likely to shake and further decrease the chance of getting the drop in (Winfield et al., 1990) .The results of this study also showed an association between female gender and difficulty, and although this was not upheld in adjusted analysis it does have clinical significance for this population group as between two and four times more women suffer from RA than men in the UK and Australia (Arthritis Research UK; National Institute for Health and Clinical Excellence, 2009) Dzeidzic and associates (Dziedzic et al., 2007) have previously studied hand function in people with arthritis and found that women had more limitations than men.

It is also noteworthy in this study that the factors associated with experiencing physical difficulty did not differ significantly between those attended an eye clinic and those who attended a rheumatology clinic, however handling and squeezing the bottle and getting the lid off were reported by a greater proportion of people with RA. Kerr and associates (Kerr et al., 2013) found that almost a third of participants reported that putting drops in was difficult. They found that the main issues for people were opening the bottle, getting drops in the eye, knowing how much was left in the bottle and remembering to instil the drops.

An association between having difficulty and using eye drops for a longer duration was also evident in this study which supports findings from previous research (Donnelly, 1987). Poor compliance with eye drop administration has been a focus of attention for many years and some conclude that providing education is the solution (Sleath et al., 2008; Kholdebarin et al., 2008), and yet, less than half of the people in the present study who attended the RA clinic had received any professional instruction. Never the less it is evident that even with high motivation to follow instructions and get the drops in some people still cannot manage. While aids are available to assist with instillation, people who reported using an aid in this study did not find it helpful.

Self-reported adherence was similar between the groups and forgetfulness the commonest reason for non-adherence, which has been reported before (Stryker et al., 2010; Chawla et al., 2007). Other research has suggested an association between adherence and ease of use (Nordmann et al., 2007) but no such association was found here, with many people in both groups reporting good adherence. Self-reported adherence has however been questioned, especially where this is non- intentional (Hahn, 2009). Stone and associates(Stone et al., 2009) found a disconnect between people’s perception of successful administration and what really happened. When observed, less than a third of people actually instilled a drop successfully without the bottle tip touching the eye (between 22% and 31%). Gupta (Gupta et al., 2012) and Robin (Robin, 2010) also observed high proportions of people failing to instil drops as prescribed and this may well lead to them giving up in frustration. Dry eye syndrome can cause people a great deal of discomfort and has also been found to influence people’s confidence (Friedman, 2010) The results in this study show that lack of confidence instilling drops was associated with experiencing difficulty. People who have RA place high value on being in control and being able to self-manage their care(van Eijk-Hustings et al., 2013) . It is therefore important for them to have confidence in their ability to self-administer eye drops and relieve a troubling symptom.

Other research suggest an association between older age and reported difficulty instilling eye drops (Kerr et al., 2013), however this was not supported in this study. More people who have RA had difficulty, and yet a higher proportion were under 60 years of age (48%). Difficulty could therefore be attributed to other factors such as reduced strength and fine motor skills as opposed to aging.

This is the first study to report the prevalence of difficulty in the self-administration of eye drops for people with RA who have dry eye syndrome. We found that the prevalence is high and much greater than for people who have eye conditions, such as glaucoma. Given that the number of people newly diagnosed with RA is increasing worldwide particularly among women (Arthritis Research UK), and that dry eye syndrome negatively impacts their quality of life, this is a significant international health issue. While the present study has a number of strengths, it is not without limitations. While the response rate was high (92 %), the non-random method of sampling from selected clinics means that sampling bias cannot be ruled out. It is possible, although very unlikely, that those who attended the clinics on days when the data was collected were different in some way from those who attended on other days. It is also possible that those who attended an RA clinic are more likely to have difficulty managing their RA, generally, than those who did not, which would give rise to an over-estimate of the prevalence of difficulty in the self-administration of eye drops. Furthermore, it is possible that bias was created because some people who attended an ophthalmology clinic also had RA or some other form of arthritis. A more significant limitation that has become evident to the researchers following data analysis and interpretation is that too few detailed questions about the handling and squeezing of the eye drop container were asked. In this study the questionnaire was assembled using questions taken from the published literature. Future studies that focus on the difficulties experienced by people with RA should ask these detailed questions so as to better inform the development of suitable interventions.

**Conclusion**

Many people who have RA experience dry eye syndrome and this significantly impacts the lives of suffers and reduces their quality of life Providing a more effective way for people with RA to self-manage symptoms of dry eye syndrome is very likely to significantly improve their quality of life. Eye drops can only be effective if people are able to instil them successfully. This is a significant issue that should be brought to the attention of occupational therapists as patients with RA are often referred to them for assessment, advice and support. More research is required to better understand the problem so that measures can be put in place to make instilling eye drops easier for everyone.

Key messages:

* Many people who have dry eye syndrome as a result of Rheumatoid Arthritis have difficulty instilling their prescribed eye drops.
* Occupational therapists are well placed to identify reduced fine motor capability and associated difficulties experienced by patients and to ensure that prescribing physicians are made aware of this
* Measures should be put in place to make it easier for people with Rheumatoid Arthritis to instil eye drops

**Ethics:**

The study was approved by the Edinburgh Napier University Faculty of Health, Life and Social Sciences Ethics and Governance Committee. 27th April 2012.

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