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An analysis of permission fees for RightsLink orders: can we better inform our clients' budgets?

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Objective: Medical Communications Agencies' clients need to budget for copyright permission costs at the outset of a project, as copyright permissions are not optional extras. However, permission fees vary greatly between publishers and usage types. I conducted an internal audit to determine whether we could provide reliable estimate ranges to clients for budgetary purposes.
Research design and methods: A total of 250 consecutive completed RightsLink orders (9 April 2016–30 August 2018) were examined. Exported data included the publisher's usage type and fee. Printable orders were reviewed to extract further details. Fees were recalculated to be nett of tax, converted to USD and a per-item usage fee was calculated for multiple requests. Usage and requestor types were pooled for ease of comparison.
Results: A total of 317 permissions were obtained from 20 different licence holders, and the total net spend on permissions during this period was $278,822. The average fee was $880/permission (range $0–$5424). Average costs for reuse in a presentation/slide kit/poster were $862 ($0–$1725) and were consistent by requestor type (agency on behalf of pharmaceutical company, $1030; pharmaceutical company $1072) but not by publisher (range $0–$1248). Reuse in a journal/magazine/newsletter cost an average of $282 (agency requestors, $604; pharmaceutical requestors, $620) and varied widely by publisher (range $0–$1035). Preliminary analyses suggest usage and requestor types correlate more strongly with licence fees than print run/audience size.
Conclusions: No. The variation in license fees between publishers for similar reuse makes it difficult for agencies to predict permissions costs on a project accurately. This analysis is limited by the RightsLink options available for different publishers, and their interpretation.

KEYWORDS
Copyright; benchmarking; legal/regulatory

An assessment of open access publishing at Shire before and after implementation of the open access publication policy

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Objective: We assessed the number of scientific, medical and technical manuscripts reporting Shire sponsored research, published with open access (OA), and the type of Creative Commons Licenses (CCLs) offered/selected, before and after the implementation of an OA publication policy at Shire in January 2018.
Research design and methods: Data on manuscripts describing Shire data published between January 2016 and August 2017 (before implementation of OA policy) and between January and June 2018 (after implementation of OA policy) in peer-reviewed journals was extracted from Datavision (Envision Pharma Group). Manuscripts pertaining to initiator-investigated research were not included.
Results: Before implementation of the OA policy, 176 manuscripts were published in 111 journals. Of these 134 (76%) were published with OA, 2 were published in journals that did not offer OA and the OA option was not chosen by corresponding authors for 40 manuscripts. In total, 49 (28%) manuscripts were published with the CC-BY license and 71 (40%) were published mostly with CC-BY-NC-ND. After implementation of the OA publication policy, 48 manuscripts were published in 43 journals, 46 (96%) published with OA and 2 (4%) without. These two manuscripts were submitted prior to OA policy introduction and were published after policy implementation due to publications time lags. Nineteen (39%) manuscripts were published with the CC-BY license, 11 (22%) were published with the C.C-BY-NC and 9 (18%) with the CC-BY-NC-ND license.
Conclusions: After implementation of Shire publication policy mandating publication of Shire sponsored research with OA, almost all of Shire's manuscripts were published as such and mostly with the CC-BY license.

KEYWORDS
Open access; policy; industry

Are journals utilizing visual imagery to increase reader engagement? A social media analysis

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Objective: Medical journals are increasingly looking to use innovative measures to promote the engagement of their readers[1]. This analysis aimed to assess the trend towards visual imagery utilization by journals on social media.
Research design and methods: Pulsar was used to analyse Twitter posts, from official journal Twitter pages, mentioning "#VisualAbstract" from 31 August 2017 to 28 September 2018. Results were filtered to include only original posts from users with the term "journal" in the Twitter bio. Journals were assessed for therapy area and region, and posts for Twitter metrics.
Results: Overall, 923 posts, from 25 journals, appeared in the initial search. Journals posting visual abstracts were predominantly surgery or general medicine journals at 36% and 28%, respectively. In our analysis more journals originated from the US vs the UK at 84% and 16%, respectively (Figure 1).
Conclusions: This research suggests that currently, visual abstracts are predominantly used by general medicine and surgery journals. Further investigation is required to determine future trends for visual imagery utilization by medical journals.

KEYWORDS
Social media; journals; abstract

Reference

[1] Fox CS, Barry K, Colbert J. Importance of social media alongside traditional medical publications. Circulation. 2016;133:1978–1983.

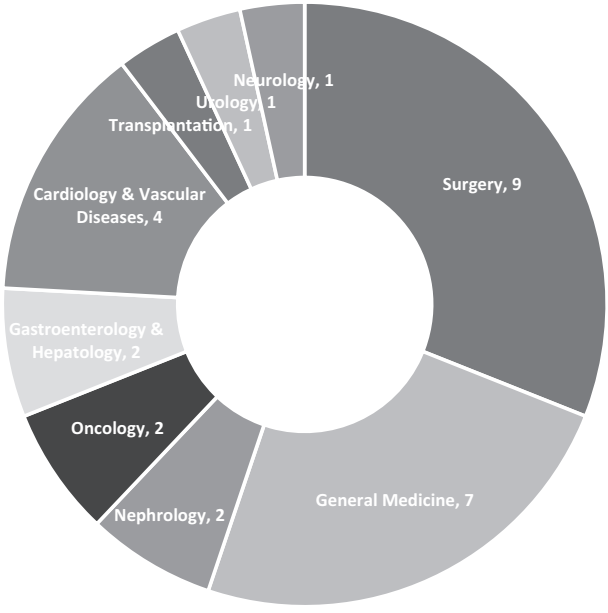

Figure 1. Proportion of journals with visual imagery Twitter posts, by therapy area, as identified by use of the hashtag "#VisualAbstract". Twitter posts ($N = 923$) were sorted by journal ($n = 25$) and journals assessed for therapy area, as determined through Journal Selector (Sylogent). Journals that were classified into more than one therapy area were sorted into up to two different categories in the analysis.

Are results from human factors studies communicated consistently and transparently?

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Objective: The design and usability of medical devices directly impact users' experience. Human factors studies (HFSs) support and evaluate the design and usability of devices by assessing the performance of end users on a set of "critical tasks" essential for safe and effective use; these studies can help users to make informed choices when selecting devices or technologies. Additionally, the FDA and EMA require a validation/summative HFS to be performed on the finalized device for regulatory approval of drug–device combination products[1,2]. Currently, there are no HFS reporting guidelines. The objective of this study was to review publications reporting HFS results to identify inconsistencies in study reporting.
Research design and methods: MEDLINE, Embase and Cochrane databases were searched on 27 July 2018 to identify validation HFSs published since January 2017 in the EU or USA. A single researcher reviewed studies against pre-defined inclusion and exclusion criteria. Congress or review publications and interventional studies were excluded. Publications were compared to investigate differences in reported study details.
Results: In total 1264 studies were identified; 13 were validation HFSs. Only 2/13 HFS titles stated that the study was validation/summative; 11/13 described the patient population; 9/13 provided a list of critical tasks assessed to demonstrate safe and effective use; 9/13 studies reported the number of critical task failures, 8/9 of these studies reported reasons for failures; 6/13 reported the number of critical task near-misses.
Conclusions: Validation HFSs are inconsistently reported, potentially making interpretation of results difficult for users. Medical writers can assist by transparently reporting HFSs. Clear reporting guidelines could improve the consistency and transparency of future HFS reporting.

KEYWORDS
Medical device; guidelines; transparency

References

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Assessment of journal compliance with data sharing guidelines from the International Committee of Medical Journal Editors (ICMJE)

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Objective: From 1 July 2018, clinical trial findings submitted to ICMJE journals must contain a data sharing statement (DSS)[1]. As part of benchmarking to inform our policy, we assessed journal compliance with ICMJE requirements over the 2 month periods before and after policy implementation.
Research design and methods: We examined articles reporting randomized controlled trials in 11 selected journals for the presence of DSSs. We compared the content of DSSs with individual items in the ICMJE guidance.
Results: The proportion of articles with a DSS was 23% (32/137) before and 25% (38/150) after 1 July, while the number of journals publishing DSSs increased from 4/11 to 7/11. Few DSSs complied fully with the ICMJE journal criteria, with 78 – 79% not referring to individual participant data (Figure 1).
Conclusions: Introduction of the ICMJE guidance did not increase the frequency of DSSs, but compliance may improve as more manuscripts submitted after 1 July are published, and journals and pharmaceutical companies implement their policies.

KEYWORDS
Data sharing; journals; transparency

Reference

[1] International Committee of Medical Journal Editors. Data Sharing [Internet] [cited 2018 Sep 12]. Available from: http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html#two.

Augmented reality pilot at congress medical booth engages health care providers on pathology and pathophysiology of key disease states

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Objective: To determine the effectiveness of using an augmented reality (AR) program to educate health care professionals who visit a congress medical booth.
Research design and methods: We piloted an AR program at a medical booth at two large neurology conferences in 2018. The program was anchored on a sculpture of a brain and delivered in HoloLens goggles. It comprised five modules, each about a different key pathology or pathophysiology underlying several neurological disease states. Congress attendees who engaged with one or more modules were asked to take a short web-based, anonymous, satisfaction survey when they finished.
Results: A total of 411 booth visitors who engaged with the AR program completed the survey. Most visitors indicated that they would recommend the experience to a colleague and that it was interesting (96% and 97%, respectively). If a new version of the program should be developed, visitors were most interested in seeing deeper scientific content (63%), followed by more interactive elements (47%) and patient stories (26%).
Conclusions: These results suggest high satisfaction with the pilot AR experience and provide support for expanding the content to further increase engagement and scientific exchange.

KEYWORDS
Digital media; education; medical communications

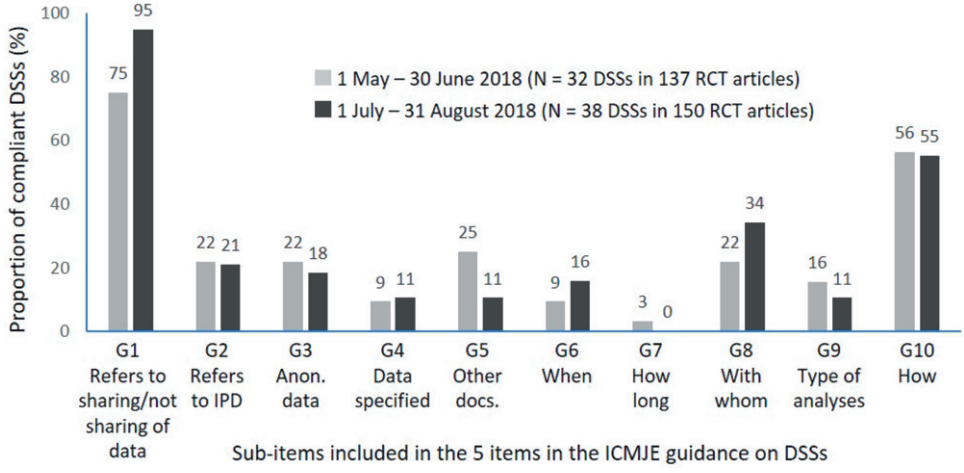

Figure 1. Compliance of data sharing statements with ICMJE guidance. The ICMJE guidance states that DSSs should indicate: (1) whether or not anonymised individual participant data will be shared (GI–3); (2) what data in particular will be shared (G4); (3) whether additional documents will be available (G5); (4) when the data will become available and for how long (G6, G7); (5) the access criteria by which data will be shared including with whom, types of analyses, and mechanism for sharing (G8–10). Included journals: *Annals of Oncology, BMJ, Endocrine-Related Cancer, JAMA Oncology, Journal of Clinical Oncology, Lancet Oncology, Lancet Neurology, Neurology, New England Journal of Medicine* (print editions) and *BMC Medicine and BMJ Open* (online). Abbreviations. Anon, anonymised; docs, documents; DSS, data sharing statement; ICMJE, International Committee of Medical Journal Editors; IPD, individual participant data; G, guidance, RCT, randomised controlled trial.

Citation rates for open-access versus pay-to-access articles in clinical journals specializing in paediatric medicine†

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Objective: Selection of open-access publishing in journals with a hybrid publication model improves reader accessibility of peer-reviewed articles compared with pay-to-access publications. Among oncology publications, use of open access was associated with a small increase in citation rates compared with pay to access[1]. To explore whether this increase applies to other specialities, we evaluated the effect of open-access publication on citation rates for articles in paediatric journals.
Research design and methods: We identified the 10 highest impact factor (IF) paediatric journals with a hybrid publication model. Citation rates for articles published in 2016 were evaluated using Scopus (www.scopus.com) on 1 September 2018.
Results: Ten of 40 paediatric journals with the highest IFs offered open-access and pay-to-access publication (IF range, 2.243–4.396). Of the 1557 articles identified, 486 (mean, 36.8%; range, 14.0–76.7%) were available via open access. No association was found between journal IF and proportion of articles offered as open access ($r^2 = 0.11$). The overall mean (SD) citation rate was 5.3 (2.29) for open-access versus 4.1 (1.21) for pay-to-access articles. There was a positive correlation between relative difference in citation rate of open-access versus pay-to-access articles and the proportion of articles published as open access ($r^2 = 0.60$).
Conclusion: Selection of the open-access publishing option in pediatric journals with a hybrid publishing model may be associated with a small citation boost for open-access articles.

KEYWORDS
Open access; journals; metrics

Reference

[1] Hassan A, Aggarwal S, Kistler J, et al. Citation rates for open-access versus pay-to-access peer-reviewed articles in clinical oncology journals. Curr Med Res Opin. 2018;34(S1):14, 15.

Defining "white paper" publications in the peer-reviewed medical literature

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Objective: White papers (WPs) are commonly regarded as policy documents presenting governmental position on a complex issue. However, the term WP is increasingly used as an umbrella term for a broad range of health policy publications in medical journals. Our objective was to define the scope and key aims of peer-reviewed articles described as WPs.
Research design and methods: We conducted a targeted literature search of the MEDLINE database via PubMed for open-access articles containing "WP" in the title, published from 1 January 2000 to 11 September 2018. Duplicates and non-WPs were excluded by a single reviewer. WPs were reviewed to identify authors' affiliations, the topic and aim(s), and the geographic regions addressed.
Results: Of 157 articles identified, 111 were included. Publication of WP articles has been increasing since 2000, peaking in 2016 with 22 open-access articles. Fifty-five per cent of WPs were authored by >1 stakeholder type; the top three were academics/clinicians (77%), the private/pharmaceutical sector (39%) and societies (32%). The WPs were mainly relevant to national/local (34%) or global (27%) audiences. A wide variety of topics were covered including: therapy and disease management (32%), research (32%), healthcare system (25%), technology (23%) and education (23%). The key WP aims were to raise awareness (67%), improve alignment (52%), educate (35%) and encourage collaboration (21%).
Conclusions: Open-access, peer-reviewed WPs are authored by various stakeholders and cover a wide range of topics. Further research using non-freely available articles, additional databases and grey literature would provide a more comprehensive characterization of WPs. Including WPs in publication plans could be effective in raising awareness of specific healthcare issues to policy makers and improving alignment globally/locally between healthcare providers.

KEYWORDS
Advocacy; literature search; policies

Developing plain language summaries of scientific congress abstracts – with patients, for patients: a feasibility study‡

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Objective: The importance of making research results more accessible and understandable to patients is being increasingly recognized. We investigated the feasibility of developing, with patients, abstract plain language summaries (APLS) for scientific congress abstracts.
Research design and methods: APLS were provided by Pfizer and Envision at the American Society of Clinical Oncology (ASCO) Annual Meeting, June 1–5, 2018. Envision developed an APLS template and selected 12 abstracts for APLS that were verified by Envision's patient partners. Each APLS was developed with plain language specialists (trained writers, designers, editors and patients), and reviewed by Pfizer experts and lead authors of corresponding scientific abstracts and accessed on a secure website, hosted by Envision, via QR codes on congress presentations.
Results: This feasibility study was successful with 12 APLS developed by Pfizer and Envision. Patients provided unique and valuable expertise reflecting patients' experiences, and met timelines.

†Encored poster at the 15th Annual Meeting of ISMPP.

‡Winner, Best Poster.

Every APLS was accessed (80% via mobile devices). APLS access peaks aligned with the corresponding research presentations. In total, there were 697 page views and 103 additional actions (57 downloads, 21 printouts, 25 redirections to scientific abstracts). APLS had significantly better readable.io scores than scientific abstracts (*t*-test: 8.8 vs 13.1; $p < .0001$). Research presenters observed attendee interest in APLS. Collectively, these results justified expansion (e.g. all Pfizer-sponsored abstracts at the European Society for Medical Oncology Congress will have APLS) and further study (e.g. APLS impact on stakeholders).

Conclusions: Developing APLS for a major scientific congress was feasible. Comprehensive, compliant and co-development processes enabled ethical and effective implementation of an innovative way to make scientific research results more accessible and understandable.

KEYWORDS
Patients; abstracts; health literacy

Does primary publication of pivotal clinical trial data influence speed of inclusion in treatment guidelines?

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Objective: Treatment guidelines inform physicians to deliver the best currently available patient care. We investigated whether timing of primary pivotal data publication for new treatments in peer-reviewed journals influences how quickly treatments are added to consensus guidelines.

Research design and methods: We analysed US new oncology treatment approvals. We searched the Food and Drug Administration website[1] for new molecular entity (NME) approvals in 2016–2017 and identified dates for: primary publication of data used per NME approval[2]; first inclusion of NME for the approval indication in National Comprehensive Cancer Network guidelines; and submission requests for guideline inclusion[3,4].

Results: Ten NMEs were identified (Table 1). Time from publication to guideline inclusion ranged from −26 to 639 (median 171) days; inclusion preceded publication in one case (acalabrutinib, based on congress abstract data). All NMEs were included following external (pharmaceutical company) requests for guideline consideration.

Conclusions: In this example, pharmaceutical company request using primary publication as evidence appears to be the main driver for guideline inclusion.

KEYWORDS
Guidelines; publication timing; Food and Drug Administration (FDA)

References

[1] US Food and Drug Administration. FDA Approved Drug Products [Internet] [cited 2018 Jan 8]. Available from: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm.

Table 1. US New Oncology Treatment Approvals 2016–2017.

Type 1 NME	Indication (brief)	Date				Time (days)			
		FDA approval	Primary publication	Submission of request for NCCN guideline consideration	NCCN guideline inclusion	FDA approval to primary publication	Primary publication to guideline inclusion	FDA approval to guideline inclusion	NCCN submission request to guideline inclusion
K®isqali (ribociclib)	HR+/*HER2*- advanced/metastatic breast cancer (in combination with aromatase inhibitor)	1 Mar 2017	7 Oct 2016	13 Mar 2017	6 Apr 2017	−145	181	36	24
Zejula® (niraparib)	Recurrent epithelial ovarian cancer	27 Mar 2017	7 Oct 2016	11 Apr 2017	12 Apr 2017	−171	187	16	1
Alunbrig (brigatinib)	ALK + NSCLC	28 Apr 2017	5 May 2017	9 May 2017	12 May 2017	7	7	14	3
Nerlynx (neratinib)	Early *HER2*+ breast cancer (post-trastuzumab)	17 Jul 2017	10 Feb 2016	17 Jul 2017	10 Nov 2017	−523	639	116	116
Idhifa® (enasidenib)	AML with *IDH-2* mutation	1 Aug 2017	6 Jun 2017	2 Aug 2017	7 Feb 2018	−56	246	190	189
Aliqopa® (copanlisib)	Third-line + treatment of relapsed FL	14 Sep 2017	14 Jun 2017	15 Sep 2017	26 Sep 2017	−92	104	12	11
Verzenio (abemaciclib)	HR+/*HER2*- advanced breast cancer with progression on previous endocrine therapy (in combination with fulvestrant)	28 Sep 2017	3 Jun 2017	28 Sep 2017	10 Nov 2017	−117	160	43	43
Calquence® (acalabrutinib)	Second-line + treatment of MCL	31 Oct 2017	11 Dec 2017	1 Nov 2017	15 Nov 2017	41	−26	15	14
Venclexta (venetoclax)	Second-line + treatment of CLL with del17p	11 Apr 2016	6 Dec 2015	12 Apr 2017	28 Sep 2017	−127	297	170	169
Rubraca® (rucaparib)	Third-line + treatment of advanced ovarian cancer with deleterious *BRCA* mutation	19 Dec 2016	29 Nov 2016	20 Dec 2016	12 Apr 2017	−20	134	114	113

Abbreviations. ALK, Anaplastic lymphoma kinase; AML, Acute myeloid leukemia; CLL, Chronic lymphocytic leukemia; del17p, 17p Deletion; FDA, US Food and Drug Administration; FL, Follicular lymphoma; HER2, Human epidermal growth factor receptor 2; HR, Hormone receptor; IDH, Isocitrate dehydrogenase; MCL, Mantle cell lymphoma; NCCN, National Comprehensive Cancer Network; NME, New molecular entity; NSCLC, Non-small-cell lung cancer.

[2] NCBI PubMed [Internet] [cited 2018 Jan 8]. Available from: https://www.ncbi.nlm.nih.gov/pubmed.
[3] The National Comprehensive Cancer Network [Internet] [cited 2018 Jan 10]. Available from https://www.nccn.org.
[4] The National Comprehensive Cancer Network; personal communication (guideline version dates provided following email request, 12 January 2018).

Does publication with open access enhance article impact?

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Objective: To assess whether open access articles received greater numbers of citations and social media attention than closed access articles.
Research design and methods: Citations (obtained using Google Scholar) and social media attention (based on Altmetric Attention Score) were obtained for all clinical trial articles (identified using PubMed) published in the specialist high impact journal *Ophthalmology* (impact factor, 7.479) during 2014 and 2015.
Results: Of 136 human clinical trial articles published in *Ophthalmology* (2014–2015), 77 were open access and 59 were closed access. Mean (standard deviation [SD]) and median (range) numbers of citations were 64.9 (87.1) and 35 (4–486) for open access articles, and 38.0 (37.7) and 32 (0–140) for closed access articles. Mean (SD) and median (range) Altmetric Attention Scores were 16.3 (78.9) and 3 (0–472) for open access articles, and 4.2 (7.7) and 2 (0–56) for closed access articles. In a small subgroup of articles filtered specifically for phase 3 trials ($n = 30$), citation number and Altmetric Attention Score were also numerically higher for open than closed access articles. Numbers of citations (but not Altmetric Attention Score) tended to increase with time since publication although correlations were very weak for both open access ($R^2 = 0.0589$) and closed access ($R^2 = 0.0016$) articles.
Conclusions: Citation numbers and social media attention for this limited series of human clinical trial articles published in *Ophthalmology* (2014–2015) suggest that both open and closed access models are utilized by researchers. Although there was a considerable overlap, the observed trend towards more citations for open than closed access articles warrants further investigation.

KEYWORDS
Metrics; open access; social media

Evaluation of plain-language summaries (PLSs): optimizing readability and format*,†

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Objective: To evaluate preferred readability and format for PLSs across indications with online audiences with different age demographics.
Research design and methods: Using top-tier journals, we identified randomized, controlled phase 3 trials and selected one article from three indications: psoriasis[1], multiple sclerosis[2] and rheumatoid arthritis[3]. For each, we wrote high-, medium- and low-complexity PLSs and produced an infographic. Different complexity levels were achieved by changing text-related variables to modify readability scores[4]. A 20-question survey was published with the PLS via UK-based patient association websites, e-mailers and Facebook patient groups.
Results: Of 167 responders, most were female and ~50% had a higher-education degree (Figure 1 on next page). For all three indications, infographic PLSs were the first-choice preference. Weighted-average preference scores showed that infographics and medium-complexity PLSs (reading age: 14–17 years) were preferred for all three indications.
Conclusion: A greater proportion of responders held a higher-education degree than was expected[5]. Preference for infographic and medium-complexity text PLS should be taken into account when communicating medical literature to the online audiences surveyed here.

KEYWORDS
Patients; survey; medical writers/writing

References

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[3] Aletaha D, Bingham CO, Tanaka Y, et al. Efficacy and safety of sirukumab in patients with active rheumatoid arthritis refractory to anti-TNF therapy (SIRROUND-T): a randomised, double-blind, placebo-controlled, parallel-group, multinational, phase 3 study. Lancet. 2017;389:1206–1217.
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[5] UK Office for National Statistics; 2011 Census Data. Table number CT0105; Highest level of qualifications and students - England and Wales [Internet] [cited 2018 Sep 24]. Available from: https://www.ons.gov.uk/census/2011census/2011censusdata

How do patients and caregivers access scientific literature?

Danielle Sheard[a], Julie Greenfield[b], Ruth Le Fevre[c], Aimée Hall[a], Annabel Griffiths[a] and Maria Haughton[a]
[a]Costello Medical, Cambridge, UK; [b]Ataxia UK, London, UK; [c]Costello Medical, Singapore, Singapore

Objective: Accessible scientific literature may help patients to manage their health conditions[1]. However, access to journal article lay summaries can be restricted. For rare diseases, scientific publications can be difficult to access and lay summaries are uncommon[2]. Our objective was to corroborate this with rare disease patients/caregivers and identify whether scientific literature accessibility is important to them.
Research design and methods: We designed a survey for ataxia patients/caregivers, to investigate accessibility and availability of

*Oral Presentation.
†Encored poster at the 15th Annual Meeting of ISMPP.

online ataxia information. This survey was conducted at the Ataxia UK 2018 Conference (6 October 2018; Derby, UK). Descriptive statistics were calculated.

Results: The 35 valid survey responses included 20/35 (57%) from patients with ataxia and 15/35 (43%) caregivers. Most (33/35, 94%) read about ataxia online: the Ataxia UK monthly e-newsletter was the most used media (26/35, 74%), while 31% (11/35) used scientific journal websites. Two-thirds (20/31, 65%) of respondents knew where to find ataxia scientific literature; only 14% (4/29) felt they did not have access to the information. Half the respondents had heard of lay summaries (17/35, 49%) and, of these, the majority (15/17, 88%) were familiar with what lay summaries are. Only 10/31 (32%) found the literature easy to understand. Other issues included lack of time/energy (14/27, 52%) and lengthy content (13/30, 43%).

Conclusions: Contrary to expectations, most ataxia patients/caregivers thought relevant scientific literature was accessible, although these conference attendees may be more informed than the general ataxia population. Even so, online information accessibility challenges included lack of time/energy, excessive length and difficulties understanding content. Lay summaries could play a valuable role in improving communication of scientific literature to patients, including dissemination via relevant charities.

KEYWORDS
Patients; access; education

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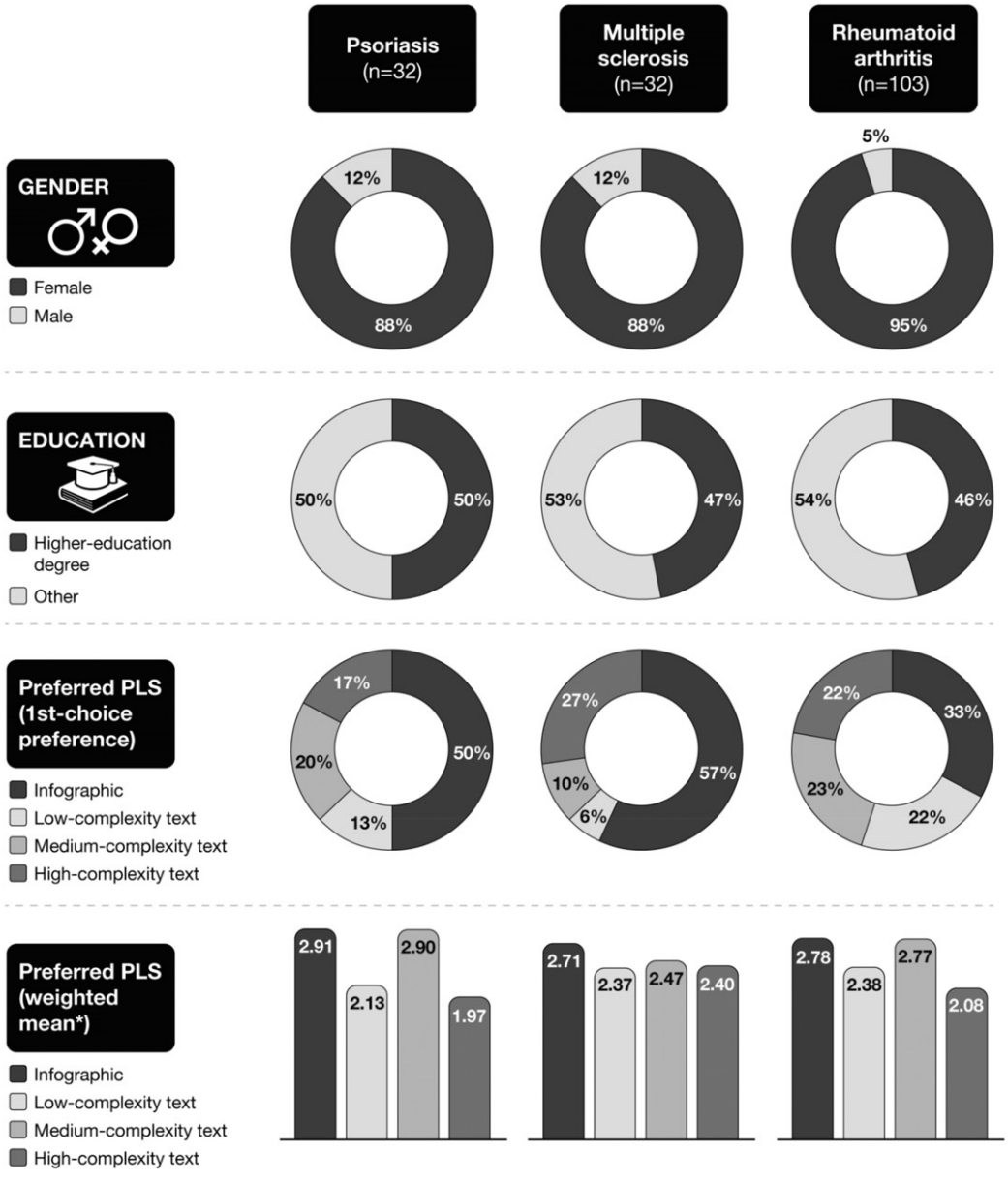

Figure 1. Plain language summary preference survey results.

The impact of data extrapolation on publication planning for etanercept and rituximab biosimilars

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Objective: Biosimilar medicines typically receive regulatory approval based on evidence of structural and functional similarity, accompanied by an abbreviated clinical programme in a selected sensitive indication(s). Approval in non-studied indications is based on the extrapolation principle, where data from the reference medicine can be extrapolated to apply to the biosimilar medicine. We investigated whether reduced availability of data resulting from the extrapolation approach was reflected in publication plans for etanercept and rituximab biosimilars currently approved in Europe.
Research design and methods: The PubMed database was interrogated using manufacturers' product codes, brand names, international non-proprietary names and "biosimilar" as search terms. No date filtering was applied. Publications clearly funded by the biosimilar manufacturers and based on data from their development programmes (analytical, pre-clinical and clinical) were identified.
Results: Two etanercept biosimilars and two rituximab biosimilars are currently approved in Europe. For each etanercept biosimilar, data has been published for a phase III confirmatory study in only one approved indication; for one of the biosimilars, a phase III study in a second indication has been published. Data from phase I pharmacokinetic and analytical characterization studies have also been published for each biosimilar. For both rituximab biosimilars, data has been published from phase III confirmatory studies in follicular lymphoma, as well as additional studies in rheumatoid arthritis; no clinical data has yet been published in full for the other three approved indications. Data from analytical characterization studies have also been published for each biosimilar. Several review articles were also identified; these did not include information on the extrapolated indications, for which no published clinical data is available.
Conclusions: There are perceived publication data gaps for extrapolated indications of etanercept and rituximab biosimilars currently approved in Europe. Publication plans for biosimilars should address the need for early and comprehensive education on the regulatory pathway for approval of biosimilars, including the concepts of extrapolation and totality of evidence.

KEYWORDS
Literature search; publication planning; pharmaceutical

Instructions for authors: are they a real help or a nightmare?

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Objective: Instructions for authors are a key issue to be considered in selecting a journal to submit a manuscript. This study aimed to evaluate the clarity and efficacy of instructions for authors from medical journals.
Research design and methods: We evaluated the instructions for authors of 100 journals, from 32 different publishers and 40 different therapeutic areas. The two or three main journals of each therapeutic area (TA) were identified and selected according to JCR 2017. Within each TA the journals had to be managed by different publishers.
Results: The main result was that we found almost 100 different sets of instructions for authors. Journals managed by the same publisher have completely different instructions. In the same therapeutic area, we couldn't find any similarity between instructions.
The most frequent issues that we found when we studied the instructions were:

- It was not easy to understand the type of articles that the journal accepted for evaluation and publication.
- Word count or page length for each article was not specified in most of the instructions. The same applies to the number of tables or figures.
- The instructions did not mention mandatory sections that the journals required for completing submission.
- Forms to be completed before submission are not available in the instructions section.
- "Conflict of interest" information and disclosure criteria differ.
- Publication fees are not specified in the instructions section.

Conclusions: Instructions should be more homogeneous and clearer. ISMPP could advocate more standard instructions to help publishers, journals and authors.

KEYWORDS
Journals; guidelines; policies

Moving beyond the printed page: the medical writer's role in creating podcasts

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Objective: Our objective was to explore the use of podcasts as an innovative, nano-learning tool and to evaluate their potential in the successful delivery of medical information to healthcare professionals.
Research design and methods: The technology to create podcasts is relatively simple nowadays. However, in our planning we initially underestimated the need for planning and production, which includes written scripts, marked up references and the requirement for a skilled medical writer. Podcasts are not off-the-cuff discussions. In order for a podcast to truly qualify as a nano-learning module, there must be valid learning objectives, the fair and balanced presentation of data and accurate referencing. The podcast must also be interesting, informative and engaging. We selected a local clinician with media training to host the series. We worked with the host to identify topics of interest. The medical writer was responsible for developing the script, prepping the speakers, verifying the data discussed, ensuring that all content was on-label, and collating and marking up references.
Results: The first six podcast episodes were recorded between March and July 2018. The first episode was released 23 April 2018 with subsequent episodes released monthly. By August, we had 337 listens and registered 109 podcast subscribers, consisting of medical practitioners (51%), nurses (46%) and pharmacists (3%). Medical practitioners by speciality were general practice

(67%); sexual health medicine (15%); neurology (7%); physician (4%); infectious diseases (3%); obstetrics and gynaecology (3%); and gastroenterology and hepatology (3%).
Conclusions: Podcasts are the perfect tool to deliver nano-learning to healthcare practitioners. The role of the medical writer is critical in developing and substantiating the content.

KEYWORDS
Healthcare professional; medical writer; technology

Open access publishing of research affiliated to Ipsen, 2013–2017: a baseline assessment*

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Objective: Publication of research with immediate open access (OA) is mandated by many funders, some of whom also require a Creative Commons Attribution (CC BY) copyright licence to facilitate reuse. This has prompted calls for OA publication of pharmaceutical industry research. Here, we evaluate OA and copyright for publication of research affiliated to a mid-sized pharmaceutical company.
Research design and methods: Data on publications from 2013 to 2017 was extracted from company bibliographies and PubMed. OA and copyright were extracted using Unpaywall and confirmed on journal websites. OA options for industry-funded research were extracted from journal websites. Proportions of articles with immediate OA (free to read on the journal website with no embargo) were compared with benchmarks from a study covering 2009–2015 (endocrinology 46% OA, oncology 56%, neurology/neurosurgery 36%)[1].
Results: In total, 220 publications were included (endocrinology/oncology 50.5%, neuroscience 38.6%, other 10.9%) from 132 journals. Of these publications, 66.4% had immediate OA (for endocrinology/oncology, 65.8%; neuroscience 67.1%; other 66.7%): 31.4% in OA journals and 35.0% in hybrid journals. Based on current policies, immediate OA would have been possible for 93.6% had a charge been paid but was not offered by journals for 1.4% because of industry funding. A CC licence was in place for 43.2% of publications, most commonly CC BY (17.3%). There were no clear trends by year or therapy area.
Conclusions: During 2013-2017, two-thirds of publications had immediate OA. Few publications were attributed a CC BY licence. Because journals would have accommodated OA for over 90% of articles, introducing a mandatory OA policy would have minimal impact on journal choice.

KEYWORDS
Copyright; open access; original research

Reference

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Patient acknowledgements in oncology trial publications*,†

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Objective: There has been an increased drive for patient-centricity within the medical industry, reinforced by the release of the US Food and Drug Administration (FDA) Patient-Focused Drug Development Guidance in 2018. While clinical manuscript acknowledgements regularly include funding, medical writing, and other professional contributions, they include trial participants less uniformly. This pilot study investigated the extent of participant acknowledgement in primary and secondary publications of clinical trials.
Research design and methods: Inclusion of participant acknowledgements in full publications (original articles) reporting primary or secondary data from prospective phase 1–4 oncology clinical trials over a 2-week period in 2012 (8–21, September 2012) was analyzed; this was repeated for 2017 (8–21, September 2017). Medline ProQuest Dialog search was used with title keywords: cancer(-s), cancerous, tumor(-s), tumour(-s), neoplasm(-s), carcinoma(-s), lymphoma(-s), leukemia(-s), or leukaemia(-s), limited to drug therap(-ies, -y, etc), administration, or therapeutic us(-age, -e, etc) in subject or title.
Results: Of 60 search results, 39 were excluded (non-English, non-clinical, non-RCT primary/secondary data original articles, reviews, letters, case reports). Of the 21 remaining articles (17 free/open access), 16 had acknowledgements sections with 10 acknowledging participants (9 primary data; 1 secondary analysis of 2 RCTs). Of the 10 articles acknowledging participants: 8 were industry-funded studies (4 acknowledging medical communications agency writing support); 8 were oncology journals (2 general/non-oncology); 9 were free/open access. In one journal, one original article acknowledged participants while another had no acknowledgements section.
Conclusions: In original articles reporting primary or secondary RCT data, participants were acknowledged in 48%. 81% were free to download or open access, therefore available to participants. 24% did not have an acknowledgements section, suggesting this is not mandated by all journals but at authors' discretion. Including a patient-centric acknowledgement statement in original publications is a simple step that recognizes the invaluable role participants play in clinical trials. Lay summaries are a further option to extend the reach to patients.

KEYWORDS
Acknowledgements; journals; patients

*This abstract has been republished with changes to the Results and Conclusions sections.
†Encored poster at the 15th Annual Meeting of ISMPP.

Quality assessment of guidelines/ recommendations developed using Delphi methodology

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Objective: The Delphi technique is often used to develop consensus guidelines and recommendations. We assessed the quality and transparency of Delphi methodology and reporting.
Research design and methods: We developed a 10 point quality assessment checklist based on reporting recommendations (Table 1)[1,2]. A PubMed search for "delphi consensus" on 21 February 2018 identified relevant studies published between 2015 and 2017. Results were screened according to pre-specified eligibility criteria. We used the checklist to assess methodological quality and transparency of reporting.
Results: Of the 267 publications identified, 90 met the inclusion criteria. Clear reporting of Delphi method (68.9%), participant diversity (55.6%) and consensus threshold (60.0%) was not explicit in all studies (Table 1). Funding source and the funder's role were described in 65.6% and 32.9% of articles, respectively.
Conclusions: There is no consistent Delphi definition, which leads to inherent flexibility and risk of bias. Transparent reporting is essential to ensure credibility, but the absence of reporting guidelines makes the development of high-quality publications challenging. Medical writers could improve quality by using a reporting checklist.

KEYWORDS
Guidelines; literature search; transparency

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[2] Brouwers MC, Kerkvliet K, Spithoff K. AGREE next steps consortium. The AGREE reporting checklist: a tool to improve reporting of clinical practice guidelines. BMJ. 2016;352:i1152.

Table 1. Quality assessment checklist.

Item	Publications clearly reporting item[a] *n/N* (%)
Methodological quality	
1. Is the type of Delphi technique used reported?	62/90 (68.9)
2. Are the methods clearly described?	80/90 (88.9)
3. Was there heterogeneity in panel membership and is the method for selection of experts clearly defined?	50/90 (55.6)
4. Were the questions formulated or validated by an expert panellist?	56/90 (62.2)
5. Was the agreement/consensus threshold predefined?	54/90 (60.0)
6. Were participants' responses in each round reported back to the group, and were responses anonymized?	35/90 (38.9)
Reporting quality and transparency	
7. Is the funding source clearly disclosed?	59/90 (65.6)
8. Is the role of the funder clearly disclosedb?	28/85 (32.9)
9. Is the funding of any external support (e.g. with the Delphi panel meeting/questionnaires, or medical writing support for the final manuscript) clearly disclosedb?	17/85 (20.0)
10. Are any conflicts of interest clearly described?	79/90 (87.8)

[a]Assessors scored each item as "yes", "no", "unclear" or "not applicable". Items were marked as "yes" if the assessor was satisfied the item was reported in full.
[b]Studies that explicitly stated "no funding" were excluded.

Where *are* biomedical research article plain-language summaries (PLSs)?[†,§]

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Objective: How best to embed and value the patient voice in all stages of drug development is a topic currently being debated across disciplines. Plain-language summaries (PLSs) are increasingly being heralded as a tool to improve communication of research to lay audiences and time-poor healthcare professionals, but this will only be achieved if PLS are intuitively located and accessible. We investigated how this "findability" is being handled by biomedical journals.
Research design and methods: As the large majority of biomedical journals do not request PLSs[1] it was challenging to determine a systematic and robust sampling methodology. The *eLIFE* list of journals/organizations that produce PLSs[2] was consulted on 12 July 2018; where multiple journals were from the same publisher, the journal with the highest impact factor was selected. Internet research explored how these journals share PLSs.
Results: Our methodology identified a sample of 10 journals from distinct publishers, plus *eLIFE* itself. Nine different terms were used to describe PLSs. Authors wrote them in 9/11 cases; seven journals required PLSs on article submission (one at revision; three on acceptance). The location/sharing mechanism varied: within articles, alongside articles (separate tab/link) and/or on separate platforms (e.g. social media, dedicated website). Where PLSs were published with articles, they were still freely accessible, even when the main article sat behind a paywall. PLSs were only included with conventional abstracts on PubMed for 2/11 journals.
Conclusions: Among a subset of the few biomedical journals producing PLSs, there is wide variation in terminology, location, sharing mechanisms and PubMed visibility. We advocate a more consistent approach to ensure that PLSs have appropriate prominence and can be found by their intended audiences.

KEYWORDS
Journals; medical publication profession; patients

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[†]CMC AFFINITY and CMC CONNECT are divisions of McCann Health Medical Communications.
[§]Winner, Most Reflective of Meeting Theme.

Who's who in rare diseases: a case study in author identification

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Objective: Identifying key opinion leaders (KOLs) can be difficult when looking to publish or establish guideline consensus, especially for researchers working in previously unfamiliar areas. This is particularly challenging in rare diseases, where there is often a need to identify a broad range of specialists to manage multi-system conditions, with only a limited number of disease-specific experts available. Using phenylketonuria as a case study, we aimed to identify KOLs by quantifying previous authorship contributions.
Research design and methods: Abstracts with the term "phenylketonuria" in their title or body text from 1 January 2016 to 19 September 2018 were identified via PubMed using a pragmatic literature review. Different variations of author names were assessed and compiled as required. Authors in the by-line of $\geq$1 publication were selected and stratified according to number of phenylketonuria publications on which they had been listed as a (first) author using R version 3.5.1.
Results: A total of 285 publications were identified, and 1400 experts were listed as authors on $\geq$1 articles. Two hundred and eighty-two, 126 and 55 participated as authors on $\geq$2, $\geq$3 and $\geq$4 publications, respectively. Seven experts co-authored $\geq$8 publications and the maximum number of publications co-authored by an individual was 16. Thirty-two, 5 and 2 had participated as first authors on $\geq$2, $\geq$3 and $\geq$4 publications, respectively. The maximum number of publications first-authored by an individual was 5.
Conclusions: By elucidating the most prominent authors in phenylketonuria, these analyses provide essential information for researchers previously unfamiliar with this disease area. Publications professionals can use this technique alongside other publications planning tools such as gap analyses and literature reviews to rigorously support authorship decisions.

KEYWORDS
Authorship; orphan drugs; publication planning